AD_______________ -

Contract Number DAMD17-94-C-4127

TITLE: Real-Time 3D Ultrasound for Physiological Monitoring

PRINCIPAL INVESTIGATOR: Richard J. Littlefield

CONTRACTING ORGANIZATION: Battelle Pacific Northwest Laboratory
Richland, Washington 99352

REPORT DATE: September 1997

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*

2. REPORT DATE
September 1997

3. REPORT TYPE AND DATES COVERED
Annual (15 Sep 96 - 14 Sep 97)

4. TITLE AND SUBTITLE
Real-Time 3D Ultrasound for Physiological Monitoring

5. FUNDING NUMBERS
DAMD17-94-C-4127

6. AUTHOR(S)
Richard J. Littlefield

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Battelle Pacific Northwest Laboratory
Richland, Washington 99352

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200*

This report documents the third year of a 4-year project to develop field prototype 3-D ultrasonic imaging system. During the reporting period, the major result was development of a third-generation sequential B-scan 3-D ultrasound telemedicine system prototype called MUSTPAC-2 (Medical UltraSound, Three-dimensional and Portable, with Advanced Communications). MUSTPAC-2 is a successor to the MUSTPAC-1, an award-winning system that was successfully field-tested in Germany and Bosnia in 1996. MUSTPAC-2 retains the operating principles of MUSTPAC-1 but is being designed to be manufacturable and FDA-approved, as well as having inproved size, weight, usability, and robustness. As of this writing, development of MUSTPAC-2 is approximately 50% complete. A working prototype is available.

14. SUBJECT TERMS Ultrasound, 3-D ultrasound, telemedicine, medical imaging, holography, volume visualization

15. NUMBER OF PAGES
66

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRAC
Unclassified	Unclassified	Unclassified	Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

RJL Where copyrighted material is quoted, permission has been obtained to use such material.

RJL Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

RJL Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

NA In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

NA For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

NA In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

NA In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

NA In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Richard J Littlefield 10/30/97

PI - Signature Date

TABLE OF CONTENTS

1. INTRODUCTION

Inexpensive, portable diagnostic imaging systems can play a key role in decreasing battlefield fatalities and reducing the cost of military health care. Ultrasound imaging is a particularly promising modality because it does not use ionizing radiation (unlike X-rays), does not require large heavy equipment (unlike magnetic resonance imaging), and has been shown through long use to be safe and effective when used by highly trained practitioners.

However, in current practice, ultrasound is basically an online two-dimensional (2-D) scanning procedure that produces a sequence of images under interactive hands-on control by the diagnostician. Each image represents a slice through the body at the corresponding ultrasound probe position. These images typically are difficult to interpret, requiring a trained ultrasonographer with years of experience to make more than the simplest diagnoses. This need for an expert interpreter makes it attractive to use ultrasound in a telemedicine setting, sending images from the patient's location to a skilled diagnostician somewhere else. However, with conventional 2-D ultrasound, considerable skill is required even to position the sensor probe, since this must be done interactively as diagnosis progresses. Thus it is problematic to use conventional 2-D ultrasound in a telemedicine setting, due to the need for a highly skilled operator to scan the patient..

Three-dimensional (3-D) ultrasound imaging offers the potential to overcome these difficulties, thus providing a diagnostically valuable, low-cost, real-time imaging modality suitable for operation and use under emergency conditions by non-specialists. Because 3-D volumes show more context than 2-D slices, it becomes easier for users to understand spatial relationships and detect abnormal conditions. Positioning the sensor so as to acquire useful images is also easier with 3-D, because volumetric data can readily be rotated and realigned to good viewing positions, largely independent of the original sensor position. This potentially allows useful 3-D ultrasound data to be taken by an inexperienced operator, then transmitted to and interpreted by a remote expert.

While 3-D ultrasound imaging has been investigated periodically for over 20 years, its adoption into routine use has been hindered by clumsy equipment, long image acquisition times, and the difficulties of visualizing the 3-D clouds of relatively noisy data produced by speckle and directional effects of ultrasound. However, recent advances in transducer array technology, computational hardware speed, and improved image reconstruction and visualization methods now appear sufficient to permit these obstacles to be overcome.

These considerations prompted Battelle to submit to DARPA, in response to solicitation BAA94-14 in early 1994, a proposal titled "Real-Time High Resolution 3-D Ultrasonic Imaging for Physiological Monitoring". This proposal laid out the vision of a three stage effort, roughly 8 years in length, leading to the development of an imaging "bed", roughly 10,000 square centimeters in size, containing an array of high resolution ultrasonic transducers and providing real-time 3-D visualization of many physiological and anatomical structures.

The first stage of this vision, and the focus of the proposal, was a 3-year project to develop a field prototype Advanced IMaging System (AIMS). This prototype would consist of a lightweight, portable ultrasonic imaging system envisioned as containing a 5 cm by 5 cm two-dimensional transducer array, computer hardware and software for real-time 3-D holographic image reconstruction and visualization, and a stereovision headset for 3-D image display. The system was envisioned as being used to rapidly detect foreign objects and bleeding in the body cavity, lungs, or extremities.

The Battelle proposal to develop an AIMS prototype was accepted by DARPA, and the project began in September 1994 with two major components:

- Research and develop advanced sensor technology, in particular, 2-D transducer arrays utilizing computational holographic focusing to acquire 3-D images in real time.
- Research and develop one or more fully functional prototype systems, suitable for clinical and/or field use, to investigate and demonstrate the utility of 3-D ultrasound as a medical imaging tool for use by non-specialist operators.

In early stages of the projects, it was planned that these two components would proceed sequentially, with the prototype system(s) being based on newly developed 2-D array transducers and thus appearing late in the project.

However, as the project progressed, it became apparent that a more productive strategy was to pursue both components in parallel, with prototype systems being based on currently available 1-D array transducer technology. This strategy was adopted in FY95 and has proved very effective.

In FY95, results in each research and development component were as follows:

- Sensor technology: Laboratory research using mechanically scanned simulations of 2-D transducer arrays confirmed that high quality images, fully focused everywhere in the 3-D field of view, could be obtained by using computational holographic focusing techniques in conjunction with large arrays (128x128) of high-frequency (5 MHz) transducers. However, the supporting electronics and computational requirements to use such large arrays appeared beyond the reach of current technology. These requirements could be met with smaller, lower frequency arrays, such as 32x32 at 1MHz. Tests at 1 MHz did not produce encouraging results when used to image commercially available plastic ultrasound phantoms of solid organs (liver and breast). However, the phantoms were not specifically designed for use at such low frequencies, so it was not clear whether the results accurately reflected the medical utility of 1 MHz ultrasound. Accordingly, it was decided to perform further testing at 1 MHz in FY96, using a different type of phantom and focusing on diagnosis of abdominal blood pooling.
- Prototype systems: a clinically usable 3-D ultrasound system based on "sequential B-scan" technology (mechanical sweep of a conventional ultrasound probe) was developed. This system was displayed at the October 1995 annual meeting of the AUSA (Association of the U.S.Army) in Washington DC, where it was favorably reviewed by many Army personnel. More importantly, the system was placed into use in the clinic of Dr.Christian Macedonia at Madigan Army Medical Center in Tacoma, Washington, for an extended evaluation to occur in FY96.

In FY96, research and development continued in both of these areas, but with a further shift of emphasis toward the development of field-usable systems.

- The most important product from FY96 was a second-generation prototype system, called MUSTPAC-1 (Medical [or Military] UltraSound, Three-dimensional and Portable, with Advanced Communications), that provides powerful telemedicine capabilities. Delivery and field demonstration of the MUSTPAC-1 was accomplished during July-September 1996. On July 8, Battelle delivered a MUSTPAC-1 system to the U.S. Army at Ft. Detrick. Following compatibility testing under supervision of the Center for Total Access (CTA, Ft.Gordon, Georgia), the MUSTPAC-1 was shipped to Landstuhl, Germany, for further evaluation. On August 7, it was deployed to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia, while a second MUSTPAC-1 remained at LRMC (Landstuhl Regional Medical Center) to serve as a receiving station. Additional secondary receiving stations were established and used at Madigan Army Medical Center (Tacoma, WA, USA), Fraunhofer Center for Research in Computer Graphics (Providence, RI, USA), and Georgetown University Medical Center (Washington, DC, USA). The MUSTPAC-1 remained in Bosnia until it was redeployed to Georgetown on Sept.8.

As a result of the success of MUSTPAC-1, a change within scope was negotiated in late FY96 that adjusted the project's priorities to reduce the level of effort on 2-D array development, emphasizing instead further development of field-usable systems based on sequential B-scan technology.

In FY97, notable accomplishments under this contract were:

1. further demonstration and publication of the prototype MUSTPAC-1 telemedicine system, including acceptance of one national award for Technology Innovation;
2. patent application for the MUSTPAC-1 architecture and system concept;
3. technical development of a third-generation prototype MUSTPAC-2 system (currently estimated 50% complete, with a working prototype available);
4. laying groundwork for technology transfer of MUSTPAC-2; and

5. continued research on sensor technology.

Further details are provided as follows:

1. Further demonstration and publication of MUSTPAC-1.

   On May 31, 1997, largely as a result of the Germany/Bosnia field demonstration, MUSTPAC-1 won the Discover Award for Technology Innovation in Computer Hardware and Electronics (Discover Magazine, Jul 97).

   Demonstrations and discussions about MUSTPAC were invited and given — mostly with funding from other organizations — at the AUSA Annual Meeting (Washington, DC, 14-16 Oct 96), the AUSA Telemedicine Conference (Tysons Corner, VA, 4-6 Mar 97), the Military Medical Capabilities Conference (Knoxville, TN, 30 May 97), Grand Rounds at Walter Reed Army Medical Center and Georgetown University Medical Center (Feb 97 and May 97), the Spanish Society of OB/GYN meeting (Spain, Jun 1997), the Society of Minimally Invasive **Therapeutics** Meeting (Japan, Jul 97), the MMVR-5 conference (San Diego, CA, Jan 97), NASA Johnson Space Center (Houston, TX, Sep 96 and Jan 97), the Tribal Healthcare 2000 Conference (San Diego, CA, 15-17 Jul 97), and the AMEDD Center and School Conference on Force Structure and Requirements in Telemedicine (Jul 1997).

   The MUSTPAC-1 has received a high level of attention and support from the public news media. Technical articles about MUSTPAC, written by magazine staff, appeared in Jane's International Defense Review (Feb 97, pg.15) and Portable Design Magazine (cover article, Jun 97). A non-technical article, associated with the Discover Award, appeared in Discover Magazine (Jul 1997, pp.74-75). These articles are provided as Appendices 3, 4, and 5 of this report. In addition many non-technical articles appeared in AP newspapers and on broadcast television, including CBS, CNBC, and The Discover Channel.

2. Patent application.

   On June 25, 1997, a patent application titled "Ultrasound Telemedicine System with Virtual Reality", was filed in support of the U.S. Department of Defense, covering

the system concept and certain details of the MUSTPAC-1 system. A copy of this patent application is provided as Appendix 2.

3. Technical development of MUSTPAC-2.

   Technical development of the MUSTPAC-2 successor system has made good progress. This effort is based on MUSTPAC-1 experiences and has the goal of developing an FDA-approved manufacturable system with improved operating characteristics. At present (October 1997), the research and development effort is approximately 50% complete. A working prototype has been assembled and is being evaluated. Further development and documentation activities are underway to make the unit manufacturable and suitable for FDA 510(k) certification. Meetings of the MUSTPAC-2 Expert Panel were held on Feb.25 and Aug.5, 1997, to discuss system development status and solicit guidance on all aspects of system development and future use. A set of high level briefing slides from the Aug.5 meeting is provided as Appendix 6. A technical overview of the MUSTPAC-2 and its development process is provided in the Section 2 of this report.

4. Technical transfer of MUSTPAC-2.

   Technical transfer of the MUSTPAC technology is an ongoing activity that combines 1) documenting, demonstrating, and discussing MUSTPAC with potential partners and users of the technology, and 2) establishing partnerships with one or more industrial companies to provide manufacturing and continued support of MUSTPAC units.

   Business discussions were held with 4 established ultrasound companies, leading to one agreement-in-principle for manufacture of MUSTPAC systems.

5. Development of sensor technology.

   An improved method was developed for computational holographic reconstruction of data obtained from a 2-D array sensor using off-axis illumination.

Additional details on MUSTPAC-2 and sensor technology are provided in the following section.

2. EXPERIMENTAL METHODS AND RESULTS

Technical activities in FY97 (October 1996 through September 1997) fell primarily in two areas:

- Sensor technology. An improved method was developed for computational holographic reconstruction of data obtained from a 2-D array sensor using off-axis illumination. This method allows off-axis spherical-wave illumination to be used, an extension over earlier techniques which supported only plane-wave illumination. In addition, a simulation study was performed to evaluate the Lockheed-Martin "BUDI" system. It was found that the BUDI system appears compatible with the new reconstruction technique. Key viewgraphs illustrating these results are presented in Appendix 8. No laboratory experimental work on sensor technology was performed in FY97, and the simulation studies comprised a relatively small part of the project (approximately 3% of expenditures).
- Development of the MUSTPAC-2 ultrasound telemedicine system as a successor to the highly successful MUSTPAC-1. This effort was the focus of the project in FY97, comprising over 90% of total expenditures. The development effort and results are described in more detail in the remainder of this section.

Appendices 1 and 2 describe the MUSTPAC-1 in considerable detail, and Appendix 7 shows an overview of the MUSTPAC-2.

In brief, MUSTPAC-2 retains the high level architecture of the MUSTPAC-1 and most of its operating characteristics, but MUSTPAC-2 has been re-engineered for improved size, weight, robustness, and usability. Almost every major subsystem has been replaced. In addition, the re-engineering process is being performed in compliance with FDA 510(k) requirements.

Specific technical changes incorporated in the MUSTPAC-2 include:

- Redesigned the 3-D Paddle electromechanical scanner to provide a fully sealed operating mechanism capable of immersion cleaning in standard disinfectant solutions. This was accomplished through the use of magnetic coupling of physical

force from the internal drive mechanism, through an impermeable aluminum shell, to an external probe carrier.

- Replaced the Silicon Graphics computer, display, and keyboard with a Pentium laptop (Toshiba Tecra 740CDT) augmented with a separate video capture card (Osprey 100).
- Converted all software to run under the Solaris operating system. Solaris is an interim step, chosen to produce an operational prototype MUSTPAC-2 on the shortest possible schedule. The operating system for the final (September 1998) version of MUSTPAC-2 will be Windows/NT.
- Extended the TeleInViVo visualization software to provide additional features requested by MUSTPAC-1 users.
- Upgraded from Immersion Probe™ to Immersion Corporation's newer EndoArm version of their MicroScribe product, for use as the MUSTPAC's Virtual Ultrasound Probe user interface device.
- Changed packaging from backpack concept to hard case with wheels.

Although these changes are conceptually straightforward, some of them proved surprisingly difficult to accomplish. Video capture was an important example. Based on discussions with vendors in 1995 and 1996, MUSTPAC development staff believed that adequate video capture capability (640x480 pixels at 15 fps or better) would be conveniently available in Pentium laptops, either built-in or as a CardBus module. However, it turned out that neither capability was developed by industry according to the projected schedule, and after several false starts, the MUSTPAC project was eventually forced to use a PCI-bus video capture card. This in turn required adding an external PCI-bus capability to MUSTPAC-2, with attendant increase in size, weight, and complexity of packaging. In addition, a significant amount of programmer effort was required to adapt vendor-supplied video capture device driver software to the special needs of the MUSTPAC project.

In retrospect, it can be seen that rapid development of the high quality MUSTPAC-1 prototype was in large part due to the availability and selection of a particularly well

suited computer platform. The Silicon Graphics Indy computer used in the MUSTPAC-1 provided an integrated system, fully supported by a single vendor, encompassing all of the required capabilities in video capture, display, computational speed, and communication software. It was a noticeable setback to the project that Silicon Graphics chose to discontinue the Indy, replacing it only with systems that were too large and heavy to be viable for continued MUSTPAC development.

As of October 1997, however, the difficulties of platform conversion have been overcome and a prototype MUSTPAC-2 system is operational. Further evaluation and development are planned for the next year, leading to completion of the MUSTPAC-2 final version in September 1998.

3. CONCLUSIONS

Success of the MUSTPAC-1 under field conditions in FY 96 provided considerable validation that 3-D ultrasound can be an effective telemedicine tool, allowing a non-specialist operator in the field to obtain high quality scans that can be interpreted by a remote expert.

In fact, development and field-testing of the MUSTPAC-1 amounted to early delivery of one major goal of the project: a prototype portable 3-D ultrasound system usable under field conditions by a non-specialist.

Much further development remains, however, to refine the MUSTPAC technology into a system suitable for routine use under a wide range of conditions. Good progress was made in this direction during FY97, with a prototype MUSTPAC-2 becoming functional in early October 1997. Development of the MUSTPAC-2 will continue in FY98, with the scheduled completion of an FDA-approved system by the September 1998.

Appendix 1:

"MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater. Final Report, 'Bosnia Task', PNL IRB # 94-6-1, Project #22258"

MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater

Final Report, "Bosnia Task", PNL IRB #94-6-1, Project #22258

Report Date: April 14, 1997

Richard J. (Rik) Littlefield
Battelle Pacific Northwest Laboratories
Richland, WA 99352

MAJ Christian R. Macedonia, MD
U.S. Army Medical Corp

ABSTRACT

Ultrasound is a popular technology for medical imaging of soft tissues because it is inexpensive, safe, and relatively portable. However, the use of ultrasound imaging in remote areas has been limited because conventional real-time 2-D (two-dimensional) ultrasound imaging requires that a highly skilled operator, capable of diagnostic decisions, be present at the patient's location to point the data acquisition probe. 3-D ultrasound data acquisition has the potential to remove this limitation, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This capability is illustrated by the MUSTPAC-1, a portable 3-D ultrasound telemedicine system recently developed for the U.S. military. In August 1996, the MUSTPAC-1 system was field-tested by the U.S. Army in Germany and Bosnia. This report discusses design and implementation of the MUSTPAC-1 system and summarizes results of the Bosnia field test.

INTRODUCTION

Ultrasound is a commonly used method for medical imaging of soft tissues. It is safe, inexpensive, and quick.

However, conventional 2-D (two-dimensional) ultrasound imaging has the significant drawback of requiring a highly skilled operator to be physically present at the patient's location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to place the image acquisition probe at the correct location and orientation to see what needs to be seen.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe so as to locate the gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient's internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing makes it problematic to use conventional 2-D ultrasound in a telemedicine setting where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound allows high quality scans to be taken by an operator with limited training and no diagnostic skills. This is accomplished by having the system scan a fairly large volume of the subject's anatomy at one time, without interpretation, so that the operator can use a simple "point-and-shoot" strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that surrounds the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done by an ultrasound expert located somewhere else.

In the summer of 1996, a prototype 3-D ultrasound telemedicine system was developed for use by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was tested using a variety of data communication links between Germany, Bosnia, and several sites in the U.S. The system worked well, experiencing no major failures and exceeding expectations in some areas.

This report discusses design and implementation of the MUSTPAC-1 system and summarizes results of the Bosnia field test.

THE MUSTPAC-1 SYSTEM

OVERVIEW. The name MUSTPAC-1 is an acronym for Medical UltraSound, Three dimensional and Portable, with Advanced Communications - 1st generation. MUSTPAC-1 is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation.

The MUSTPAC-1 system is optimized for use in a telemedicine framework. It provides the unique capability that high quality ultrasound scans can be taken by an operator with no diagnostic skills, little training, and no online connection to an expert.

Typically MUSTPAC-1 is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across their skin over the area of interest (Figure 1). During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric dataset of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.

Figure 1. Acquiring a 3-D abdominal scan using the 3-D Paddle and actual ultrasound probe.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician.

Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D dataset simply by moving the probe as if they were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.

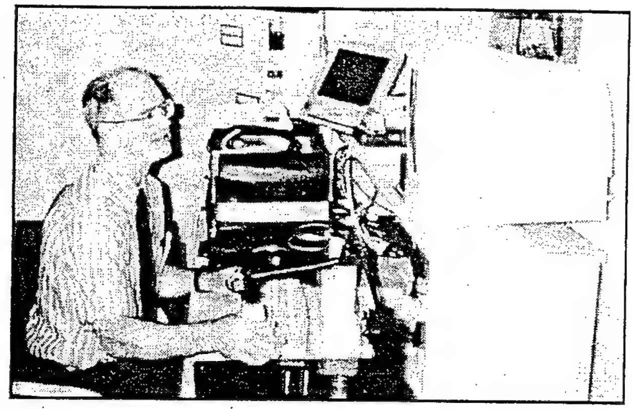


Figure 2. Interpreting a 3-D scan using the Virtual Ultrasound Probe at a diagnostic workstation.

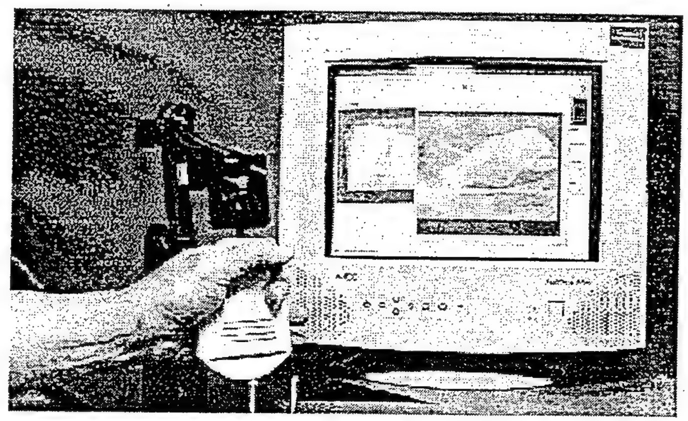


Figure 3. Closeup of the Virtual Ultrasound Probe and diagnostic workstation display.

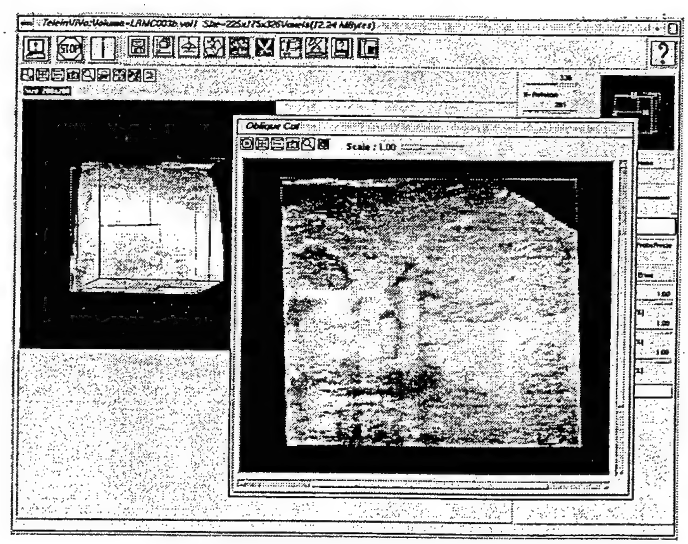


Figure 4. Actual diagnostic display (human liver with clotting in major veins).

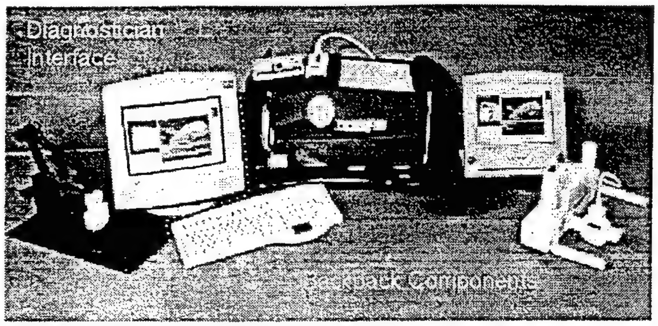


Figure 5. MUSTPAC-1 system components as packaged for military field evaluation.

SYSTEM COMPONENTS AND PACKAGING. Major components of the MUSTPAC-1 system are shown in Figure 5. These components include (right-to-left):

- Backpackable field unit containing "3-D Paddle" electromechanical scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display (to right of backpack)
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)
- Keyboard with integral touchpad (in front of backpack)
- High-resolution color monitor.
- Virtual ultrasound probe
- TeleInViVo™ visualization software (a product of Fraunhofer CRCG, Providence RI, customized for MUSTPAC-1).
- Other custom software for data acquisition and control.

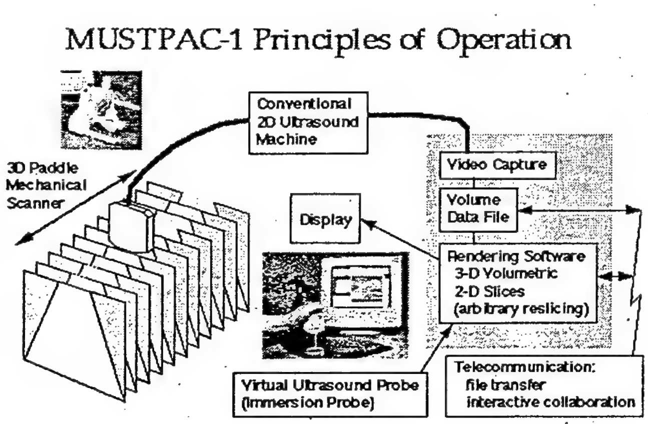


Figure 6. Major components, operations, and data flows in MUSTPAC-1.

PRINCIPLES OF OPERATION. Figure 6 diagrams the major components, operations, and data flows within the MUSTPAC-1 system.

Scanning. Volumetric scanning is done by mechanically moving the probe of a conventional off-the-shelf ultrasound machine (Hitachi EUB-905). As the probe moves, the ultrasound machine generates a sequence of video images showing a 2-D slice of the subject under the probe. A computer digitizes the sequence of 2-D images and assembles them to form a 3-D volumetric dataset.

Moving the ultrasound probe is accomplished by using an electromechanical device attached to it. In the MUSTPAC-1, this device is called the "3-D Paddle". It is a battery-powered device that moves the probe under motor control, in a straight line, at a precise speed of 1.0 cm/second. This linear scanning movement generates a set of parallel images that naturally assemble to form a dense rectangular 3D dataset.

Scans are usually taken at 15 fps (frames per second), using a 3.5 MHz or 5 MHz convex-face sector-scan probe. With typical penetration depths, this results in scanning a region 6 cm wide at the skin surface and 20 cm wide at 15 cm deep, with a voxel (volume element) size of 0.7 mm on each axis.

It is important to note that the 3-D datasets captured by this process represent a sort of "snapshot" of the subject's anatomy. Anatomical movement is not captured, except in the form of motion artifacts that the diagnostician must learn to ignore.

In addition to the 3-D ultrasound dataset generated during the scan, the MUSTPAC-1 also captures a single-frame image from each of two attached video cameras. Typically these are used to record placement of the 3-D Paddle on the subject's body.

Visualization for Analysis and Diagnosis. The MUSTPAC-1 can generate several kinds of images:

* 2-D slices at arbitrary positions and orientations.
* 3-D volumes using "maximum intensity projection" (MIP) and similar techniques for combining the values of dataset volume elements (voxels).
* 3-D surfaces defined by threshold values and rendered using one of several shading techniques.

Several images can be shown simultaneously. The most common practice is to combine a large 2-D slice image with a small 3-D volumetric image (Figure 4). The 2-D slice shows detail that is useful diagnostically,

while the 3-D volumetric image provides context by showing location of the 2-D slice within the volume.

Virtual Ultrasound Probe. To provide diagnosticians with a familiar, convenient user interface, the MUSTPAC-1 is equipped with a Virtual Ultrasound Probe (Figure 3). This is a hand-held 6-D input device that controls 2-D slicing of volumetric datasets in the same way that a real ultrasound probe controls 2-D imaging of patients. That is, theVirtual Ultrasound Probe looks, feels, and acts like a real ultrasound probe in that the on-screen image is constantly updated in real time (typically 5-10 times per second) to reflect the position and orientation of the probe. (Again, this real time updating does not reflect anatomical movement, which is not captured in the datasets).

In the MUSTPAC-1, the Virtual Ultrasound Probe is implemented using an Immersion Probe™ (product of Immersion Corporation) with a dummy ultrasound probe added to it. Other 6-D input devices, such as magnetic free-space trackers, could easily be substituted for the Immersion Probe™.

Data Communication. The MUSTPAC-1 system provides two major methods of data communication: batch mode file transmission and TeleInViVo™ incremental transmission.

In batch mode file transmission, 3-D datasets and associated files are transferred using the Internet standard "ftp" protocol. These transfers are for ease of use over relatively high bandwidth communication channels. They are initiated by the user from a "desktop" graphical interface using a drag-and-drop procedure.

Incremental communication capabilities are also built into the TeleInViVo visualization program. These capabilities allow all or part of the full dataset to be transferred quickly at reduced resolution, while the user interactively evaluates the images. Typical use is envisioned to be transfer of the entire dataset with resolution reduced by 4X per axis (64X overall), followed by transmission of an identified region of interest at the full resolution of the dataset.

Image Quality. The MUSTPAC-1 produces diagnostic quality images.

At maximum resolution, the saved 3-D datasets capture all detail present in the video output signal from the Hitachi EUB-905 (640x480 pixels at 8-bit gray scale). However, maximum resolution capture often is not justified due to noise and fuzziness in the ultrasound imaging process.

Better results are usually obtained by a simple process that filters the digitized images and samples the filter output to construct the saved 3D dataset. Operator controls are provided to select the amount of filtering. Typical settings produce one dataset voxel as the average of a 2x2 block of pixels from the digitized video image.

There is no image degradation due to storage and transmission of the 3D datasets. All transmission protocols incorporate error detection and correction/retransmission. Only non-lossy (exact) compression techniques are used in the MUSTPAC-1.

FIELD EXPERIENCES. In August, 1996, the MUSTPAC-1 system was deployed by the U.S. Army to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia. A second MUSTPAC-1 placed at the Army's Landstuhl Regional Medical Center in Germany served as the primary receiving station.

Scanning. During the deployment, a total of 72 scans were performed on 42 volunteers, as follows:

Scan Type	**Number**
Right Upper Quadrant	55
Pelvis/Uterus/Posterior Cul-de-Sac	7
Placenta	5
Renal	3
Extremity	1
Aorta	1
Total	**72**

Most of these scans were taken by operators with no ultrasound diagnostic skills and minimal MUSTPAC-1 training (typically 10 minutes). No formal evaluation of the image quality has yet been performed. Informal evaluation by a variety of experienced ultrasound users suggests that the quality of the scans was largely independent of an operator's level of training and generally ranged from adequate to very good.

Communications. Most transfers between Bosnia and Germany were performed using ftp over a T1/E1 (roughly 1 megabit/second) geosynchronous satellite link leased by the Army. Despite a round-trip packet delay of 580-600 ms, net transfer rates of roughly 50 Kbytes/second were routinely achieved. Thus typical 3-D datasets of 6-12 Mbytes required only a few minutes to transfer even without compression.

As exercises, 3-D datasets were also transferred over two slower communication links. One of these links was between Germany and Washington DC (USA) at 56 Kbits/sec using the International Maritime Satellite System (INMARSAT) and its associated telephone system ISDN link. The other was between Bosnia and Germany using the Army's Tactical Packet Network

(TACNET) at 9.6 Kbits/sec. These transfers were also successful, but would be too slow for most routine applications without the use of more aggressive data compression techniques.

Diagnostic Usability. During the Bosnia deployment and in the 6 months since its completion, the MUSTPAC-1 system has been operated by approximately 20 experienced ultrasound users. Informal evaluation suggests that the system is very easily learned. One striking observation is that no experienced ultrasound user to date has required more than 5 minutes practice with the Virtual Ultrasound Probe to begin making medical interpretations of 3-D scans that they had not previously seen. However, no formal studies of usability or effectiveness have been performed, and such studies will be needed to determine the degree of diagnostic accuracy provided by the MUSTPAC's techniques.

Adverse Events. During the field test in Bosnia, one subject was physically pinched by the 3-D Paddle, resulting in a small superficial bruise requiring no medical treatment. The operational procedure for the 3-D Paddle was immediately revised to avoid a repetition, and the 3-D Paddle has been redesigned to make pinching less likely in future designs.

LIMITATIONS. While MUSTPAC-1 provides a unique capability for ultrasound telemedicine, it is a first-generation system with significant limitations. These limitations include:

- No Doppler. Neither the Hitachi EUB-905 ultrasound scanner nor any of the MUSTPAC-1 software supports any Doppler capability at this time. This means that MUSTPAC-1 provides no direct visualization of blood flow.

- Inflexible scanning. The motor-driven 3-D Paddle is simple to use and robust, but provides only linear translation parallel scanning. Freehand scanning would be more flexible and simpler to use in many parts of the body.

- No anatomic motion. Conventional real-time 2-D ultrasound shows anatomic motion, such as pulsing arteries, as a moving image on screen. This is diagnostically useful. However, the 3-D scans captured by MUSTPAC-1 are static snapshots. Generally speaking, with MUSTPAC-1 anatomic motion produces image artifacts that the diagnostician must ignore.

Ongoing development of the MUSTPAC system is planned to relieve these limitations.

SUMMARY

3-D ultrasound data acquisition can potentially enable effective use of ultrasound imaging in a telemedicine setting, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This capability is illustrated by the MUSTPAC-1, a portable 3-D ultrasound telemedicine system recently developed for the U.S. military and successfully field-tested by the U.S.Army in Germany and Bosnia in August 1996.

ACKNOWLEDGMENTS

Development and testing of the MUSTPAC-1 was funded by the Defense Advanced Research Projects Agency (DARPA) under contract number DAMD-17-94-C-4127. We are grateful to our program managers Dr. Rick Satava and Dr. Wally Smith for their support and guidance.

The opinions expressed in this article are those of the primary authors and do not necessarily reflect official policy of the United States Department of Defense or Department of Energy.

ADDITIONAL SOURCES

"MUSTPAC-1: 3-D Ultrasound Telemedicine System", `http://www.pnl.gov/3dmed`, Dec.1996.

"Backpack remote medicine proves its worth", Jane's International Defense Review, Feb.1997, pg.15.

IEEE Engineering in Medicine and Biology Magazine, Theme Section titled "Advances in Ultrasound", V.15, No.6, Nov/Dec 1996, pp.18-101.

Appendix 2:

Patent Application: "Ultrasound Telemedicine System with Virtual Reality"

Patent Application:
"Ultrasound Telemedicine System with Virtual Reality"

Filed by Battelle in support of
U.S. Department of Defense
DARPA project DAMD17-94-C-4127
"Real-Time High Resolution 3-D Ultrasound Imaging for Physiological Monitoring"
Battelle Project No. 22258, Patent File No. G-298
June 1997

Point of Contact:
Richard J. (Rik) Littlefield
Battelle / PNNL
Richland, WA 99352
voice 509-375-3927
email: rj_littlefield@pnl.gov

ULTRASOUND TELEMEDICINE SYSTEM WITH VIRTUAL REALITY

This invention was made with Government support under a contract awarded by the U.S. Department of Defense. The Government has certain rights in the invention.

FIELD OF THE INVENTION

The present invention relates generally to a method and apparatus for obtaining medical ultrasound images remotely and manipulating the medical ultrasound images for diagnosis.

BACKGROUND OF THE INVENTION

Ultrasound imaging began in the 1950's and slowly developed from A-mode systems to real-time imaging used today in obstetrics, and diagnosis and management of disease. Presently in use are ultrasonic systems viewing in two dimensions. The two-dimensional systems are dependent upon the experience and skill of the operator to obtain an optimal position of the ultrasound transducer to obtain an adequate image of the anatomy of interest. This is because of the inherent geometric constraints when using a spatially flexible 2-D imaging technique to view 3-D anatomy. In practice, the operator of an ultrasound transducer or scanner is trained as a physician, radiologist, or ultrasound technician with several years of specialized training. Because of the scarcity of skilled operators, patients are often transported, thereby delaying

examination. Thus, whether the ultrasonic probe is proximate or remote to the physician, the skilled operator must accompany the patient for adequate 2-D images.

Efforts have been made to obtain ultrasound examinations remotely via telemedicine. A conventional real-time 2-D ultrasound imaging system is combined with a video teleconference system wherein an operator located with the patient positions the scanner and the subsequent ultrasound image is transmitted to the physician who may request changes in scanner or probe position for optimal viewing of the anatomy of interest. Unless the operator is already trained to perform ultrasound examinations independently, he is dependent upon the physician's instructions to position or reposition the scanner or probe. Thus the feedback loop that controls probe position based on image interpretation includes two people who must communicate by language. Because the person who interprets the images does not have direct physical control of the probe position, the time needed to perform the examination using this approach is greatly increased and the quality of the exam may be significantly decreased.

Research has developed 3-D imaging techniques that reduce variability of the 2-D techniques and to permit a physician to view 3-D images via virtual ultrasound probes. For data acquisition, there have been developed articulated arms, free-space magnetic position sensors, circular arc scan, parallel scan, and image derived position. Others have digitized ultrasound data into a 3D digital database. Graphic visualization either as volumetric images or 2D slices has been achieved. A 3D viewing system has been developed for training by MedSim. In the MedSim viewing system, a volumetric ultrasonic image is loaded onto a computer and the computer fitted with a virtual ultrasound

probe implemented using a free-space magnetic position sensor. Students call up the volumetric ultrasonic image dataset on the computer, and with the virtual ultrasound probe controlling a 2-D image, explore the volumetric ultrasonic image dataset on the computer screen. The same volumetric image dataset is used repeatedly for numerous students.

However, to date, a system that integrates the functions of scanning, transmission, reception and interpretation under a user interface permitting an unskilled operator to quickly and easily obtain 3D ultrasound datasets and transmit them to a skilled diagnostician for interpretation/diagnosis has not been assembled.

Thus, there remains a need for an ultrasonic imaging system that can be operated by an unskilled operator yet produce images interpretable by a skilled physician.

SUMMARY OF THE INVENTION

The present invention is an apparatus for ultrasound telemedicine, that combines 3-D ultrasound data acquisition with a virtual ultrasound probe and a communication link to provide volumetric data that can be viewed as either 2-D or 3-D images. More specifically, the apparatus has

(a) an ultrasound probe having a transducer for converting an electrical signal to an ultrasonic signal and for converting a received reflected ultrasonic signal to a received electrical signal;

(b) a position sensor providing spatial coordinates for a position of the ultrasound probe;

(c) a medical ultrasound unit that sends a plurality of electrical signals and receives a plurality of

[redacted]

received electrical signals and converts the plurality of received electrical signals into a plurality of 2-D reflected image signals;

(d) a first computer (on-site computer) having software instructions that combines the plurality of 2-D reflected image signals into a volumized data set, said first computer further having a communication link for transmitting the volumized data set to a remote location; and

(e) a second computer (diagnostic computer) at the remote location that receives the volumized data set from the communication link and creates a three dimensional model from the volumized data set.

The apparatus preferably further has a virtual ultrasound probe connected to the computer at the remote location, for viewing cross sections of the three dimensional model. An advantage of using the virtual ultrasound probe is that the diagnosing physician is already familiar with actual ultrasound probes and requires but a few minutes practice to effectively use the virtual ultrasound probe.

It is an object of the present invention to provide an apparatus for ultrasound telemedicine that permits acquisition of ultrasonic image data from a patient by an unskilled operator while producing ultrasonic images interpretable by a trained physician.

The subject matter of the present invention is particularly pointed out and distinctly claimed in the concluding portion of this specification. However, both the organization and method of operation, together with further advantages and objects thereof, may best be understood by reference to the following description taken in connection

with accompanying drawings wherein like reference characters refer to like elements.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic of an ultrasound telemedicine system according to the present invention.

FIG. 1a is an expanded schematic of the field equipment.

FIG. 1b is an expanded schematic of the diagnostic equipment.

FIG. 1c is a photo of a computer screen capture showing four views of a 3-D ultrasound data set of a phantom breast, with an overlapping view of an orthogonal view of an oblique cut through the 3-D ultrasound data set.

FIG. 2a is a block diagram of software and data files.

FIG. 2b is a block diagram of software.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

Referring to FIG. 1 the apparatus of the present invention for ultrasound telemedicine, has:

(a) an ultrasound probe 100 with a transducer for converting an electrical signal to an ultrasonic signal and for converting a received reflected ultrasonic signal to a received electrical signal;

(b) a position sensor (not shown) providing spatial coordinates for a position of the ultrasound probe;

(c) a medical ultrasound unit 102 that sends a plurality of electrical signals and receives a plurality of received electrical signals and converts the plurality of received electrical signals into a plurality of 2-D reflected image signals;

(d) a first computer 103 having software instructions that combines the plurality of 2-D reflected image signals into a volumized data set, the first computer 103 further having a communication link 104 for transmitting the volumized data set to a remote location; and

(e) a second computer 106 at the remote location that receives the volumized data set from the communication link 104 and creates a three dimensional model from the volumized data set.

The ultrasound probe 100 may be any ultrasound probe including but not limited to Hitachi EUP-C324T.

The position sensor may be any position sensor including but not limited to articulated arms (e.g. Immersion Probe, Immersion Corporation, San Jose, CA), free-space magnetic position sensors (e.g. Flock of Birds sensor, Ascension Technology Corp., Burlington, VT), circular arc scan, parallel scan, and image derived position. In a preferred embodiment, the position sensor is a parallel scan linear scanner that is electrically motor driven. Alternatively, a 2-D array of ultrasound transducers with physical or computational focusing (ultrasound holography) may be used.

The medical ultrasound unit 102 may be any medical ultrasound scanner including but not limited to Hitachi EUB-905.

The first computer 103 may be any computer, but is preferably a 150 MHZ or faster, 80 MB memory or larger, fast floating point computation, multiprocessing operating system with a window-based graphical user interface. Examples include but are not limited to Silicon Graphics Indy computer running the Irix operating system and a Pentium processor laptop computer running Solaris or Windows/NT. FIG. 1a shows additional details of the first computer 103

[redacted]

and its relationship to the medical ultrasound unit 102 and the ultrasound probe 100, and the position sensor 107, (optional position sensor 107a attached to the second computer 106). It will be apparent to those of skill in the art that the medical ultrasound unit 102 and the first computer 103 may be either in an integral package/housing or in separate packages/ housings.

The communication link 104 may be any communication link including but not limited to telephone communication, satellite communication, radio communication, and a combination thereof. A preferred communication link is within the first computer 103, specifically a 10BaseT Ethernet.

The second computer 106 may be any computer, but is preferably a computer as specified above for the first computer 103. The second computer 106 (FIG. 1b) has communication link software, preferably 10BaseT Ethernet, permitting receipt of data transmitted from the first computer 103.

The three dimensional model may be a volumetric model or a 2D slice model wherein the volumetric model is preferred.

The second computer 106 may have attached a virtual ultrasound probe 108 permitting manipulation of a 2-D plane through the three dimensional (3-D) model on the display 110 of the computer. The virtual ultrasound probe 108 is a multi-degree, preferably 6-degree, of freedom spatial positioning input device and associated software, for example an articulated arm, free-space magnetic position sensor, or other hardware familiar to ultrasound diagnosticians. Specifically, an articulated arm was obtained and fitted as the virtual ultrasound probe 108. Specifically, an Immersion Probe with a stylus at the

moveable end of the articulated arm was modified by replacing the stylus with a mock-up of an ultrasound probe. In addition, the base that the arm is attached to was replaced to maintain position calibration. Finally an interface software program was added to transfer x, y, z, pitch, roll, and yaw from the mock-up ultrasound probe to the cutting plane on the computer screen.

FIG. 1c, upper left, shows volumetric visualization 111 of an entire 3-D dataset 112 with a 2-D cutting plane 114. The location of the 2-D cutting plane 114 within the 3-D dataset 112 is indicated by outline and also by emphasizing the cross section defined by the cutting plane. Through software interpretation, the logical position and orientation of the cutting plane is made to track the physical position and orientation of the virtual ultrasound probe input device, so that as the user moves the probe left, the cutting plane moves left, and so on. The image is of a breast phantom of silicone plastic with simulated cysts molded therein. Additionally, FIG. 1c, upper right 120, lower left 122 and lower right 124 are views orthogonal to the y-z, x-z, and x-y planes respectively. In the extreme upper right of FIG. 1c is a line drawing 125 showing the view angle of the 2-D cutting plane. Also shown overlapping (FIG. 1d) is a perpendicular or orthogonal view 126 of the cross section 116; the perpendicular view 126 avoids image distortion compared to an angular view. The orthogonal view is generated by a software instruction set, preferably part of the visualization software (FIG. 2a 208, 206). In FIG. 1c, the upper left window shows a volumetric rendering of the entire 3D dataset, with the position of the cutting plane The largest window shows the cross section in perpendicular view, so that it is not distorted.

[redacted]

Both computers 103, 106 have software instruction sets (FIG. 2a) for capturing, displaying, transferring/sharing, and printing graphical data. The medical ultrasound unit 102 generates 2-D data in the form of a slice through an anatomical feature. By collecting a plurality of 2-D data sets in the form of substantially contiguous slices, a 3-D data set can be obtained. Each 2-D slice or frame may have 640 X 480 pixels with 30 frames per second.

The medical ultrasound unit 102 converts ultrasonic signals into digital data in a proprietary format then converts the proprietary format digital data into a standard analog video format. Data from the medical ultrasound unit 102 may be transferred to the first computer 103 either as proprietary format digital data or in standard analog video format. While it is simpler to use the standard analog video format, greater quality of imaging is achieved using the proprietary format digital data directly.

When the standard analog video format is used, the frames are captured on a video capture card 200 within the first computer 103. The video capture card may be any standard video capture card, for example a Silicon Graphics VINO subsystem. Optionally, the second computer 106 may have a video capture card 200a. Standard video capture software is able to receive frame data from the video capture card and display the 2-D image. However, that is not sufficient for 3-D visualization or rendering. Accordingly, a standard video capture software was modified to include storing each 2-D data frame and volumizing the 2-D data frames to obtain a 3-D volumized data set, as a video capture and volumization software 202, 202a. The 3-D volumized data set is preferred because it is a standardized geometry including scaling parameters. The video capture software was prepared from Silicon Graphics' online

reference documentation, IRIS Digital Media Programming Guide, Chapters 11-14 on an Indy computer having a VINO (Video Input No Output) subsystem.

Whether from proprietary format digital data or from standard analog video format, data volumization from 2-D slices is preferably done according to the following steps:

(a) establish scaling parameters that describe voxel sizes, in other words, number of pixels per unit length within each frame and separation unit length between frames;

(b) filter the image to reduce the volume of data; and

(c) write the filtered data (3-D volumized data set) (e.g. VOL1 file format) to disk with headers and trailers describing image size and scaling in a format compatible with the visualization software 206.

Pixels per unit length may be determined by examination of scale lines and tick marks inserted into the image data by the medical ultrasound unit. The examination may be manual supported by a graphical user interface, or automatically by software providing image interpretation. Separation unit length may be determined by the speed of a position sensor and the frame capture rate.

Filtering of the data may be done by computing spatial averages within a neighborhood of pixels within each 2-D image and/or between nearby frames, storing only the averages instead of all captured pixel values. The exact settings (filter parameters) are preferably operator controlled/ selected. Preferred settings are averaging 2X2 blocks of pixels within each frame, and collecting 15 frames per second with no averaging resulting in an 8-fold reduction of data compared to using all pixels captured at 30 frames per second. Further data compression may be accomplished using more sophisticated methods, including but

not limited to wavelet compression techniques, for example Joint Photographics Experts Group (JPEG) compression.

Once the 3-D volumized data set is made, there are two options with respect to further processing to produce viewable images: (1) transmit the 3-D volumized data set via file transfer software 204 in the first computer 103 to the file transfer software 205 in the second computer 106, (2) use visualization software 208 in the first computer 103 to create a 3-D visualization data set in the first computer 103, then connect with the visualization software 206 in the second computer 106 and share the 3-D visualization data set between both computers. A further option is encryption of either (1) or (2) prior to transmission or sharing with encryption software 210, 212. Visualization software must be visualization software which has an interface with a virtual ultrasound probe 108, for example TeleInViVo, Fraunhofer CRCG, Providence, RI. Whichever visualization software is used, the 3-D volumized data set must be in a format compatible with the visualization software. Once a 3-D visualization data set has been created, the visualization software 206, 208 may call the 3-D visualization data set as many times as desired for observation of the graphical image on a screen. The screen view is updated in real time (5-10 updates per second) as the virtual ultrasound probe 108 is moved.

Encryption software 210, 212 may be any encryption software, for example as available from RSA Redwood City, CA or PGP San Mateo, CA. In a preferred embodiment, the encryption software 210, 212 is capable of international use inasmuch as the location of an injured or disabled individual may be in a different country compared to the remote location of a diagnosing physician.

Beyond sharing image data, it may be necessary for a diagnosing physician at the remote location to communicate observations, instructions or interpretations to the on-site operator. Accordingly, both computers 103, 106 preferably include videoconferencing software 230, 232.

Specific instructions for each of the four functions of capturing, displaying, transferring/sharing, and printing are preferably encoded in a general graphical user interface (GUI) FIG. 2b 214, 216. Options include an on-line tutorial 218, 220, printer software 222, 224, and a medical library 226. The printer software 222, 224 preferably is an interface permitting a user to print or output a screen, window, body of text, and/or graphic or picture. The print may be directed to a file or a printer.

The graphical user interface 214, 216 is a captured user environment, controlled by a user login ID, and driven by the operating system native desktop manager. The graphical user interface 214, 216 has icons for operating the videoconferencing software 230, 232, video capture software 202, visualization software 206, 208, file transfer software 204, 205, encryption software 210, 212, on-line tutorial 218, 220, printer software 222, 224, and medical library 226, 228. The graphical user interface 214, 216 further includes a file manager (not shown) permitting navigating though directories, manipulating (finding, creating, copying, moving, deleting) files, dragging and dropping between and within windows. The graphical user interface 214, 216 further includes archiving for storing ultrasound datasets in random access removable media, as well as documenting for storing textual information with the ultrasound data sets, and video monitor controlling for switching monitor configurations for alternate displays.

Although the invention has been described in terms of 3 spatial dimensional data, it will be apparent to one of skill in the art that time dependent data may also be used. The hardware would be the same, and the software would simply be modified to accept the time parameter.

Closure

While a preferred embodiment of the present invention has been shown and described, it will be apparent to those skilled in the art that many changes and modifications may be made without departing from the invention in its broader aspects. The appended claims are therefore intended to cover all such changes and modifications as fall within the true spirit and scope of the invention.

CLAIMS

We claim:

1. An apparatus for ultrasound telemedicine, comprising:

(a) an ultrasound probe having a transducer for converting an electrical signal to an ultrasonic signal and for converting a received reflected ultrasonic signal to a received electrical signal;

(b) a position sensor providing spatial coordinates for a position of the ultrasound probe;

(c) a medical ultrasound unit that sends a plurality of electrical signals and receives a plurality of received electrical signals and converts the plurality of received electrical signals into a plurality of 2-D reflected image signals;

(d) a first computer having software instructions that combines the plurality of 2-D reflected image signals into a volumized data set, said first computer further having a communication link for transmitting the volumized data set to a remote location; and

(e) a second computer at the remote location that receives the volumized data set from the communication link and creates a three dimensional model from the volumized data set.

2. The apparatus as recited in claim 1, further comprising a virtual ultrasound probe connected to the computer at the remote location, for viewing cross sections of the three dimensional model.

3. The apparatus as recited in claim 1, wherein the software instructions comprise a video capture and volumization software that receives the plurality of 2-D

reflected image signals as a plurality of frames, each of the plurality of frames volumized with respect to adjacent frames to produce the volumized data set.

4. The apparatus as recited in claim 3, wherein the software instructions further comprise a 3-D visualization software that receives the volumized data set and produces a 3-D visualization data set.

5. An apparatus for viewing a 2-D cross section of a 3-D dataset comprising:

(a) a diagnostic computer with a screen for displaying the 3-D data set, the diagnostic computer further having software for generating a 2-D plane viewable on the screen simultaneously with the 3-D dataset;

(b) a virtual ultrasound probe with an interface software program that transfers physical position of the virtual ultrasound probe to the logical position of the 2-D plane defining a 2-D cross section through the 3-D dataset;

(c) a software instruction set permitting an orthogonal view of the 2-D cross section of the 3-D dataset at the location of the 2-D plane.

6. The apparatus as recited in claim 5, further comprising an apparatus for ultrasound telemedicine, comprising:

(a) an ultrasound probe having a transducer for converting an electrical signal to an ultrasonic signal and for converting a received reflected ultrasonic signal to a received electrical signal;

(b) a position sensor providing spatial coordinates for a position of the ultrasound probe;

(c) a medical ultrasound unit that sends a plurality of electrical signals and receives a plurality of received electrical signals and converts the plurality of received electrical signals into a plurality of 2-D reflected image signals; and

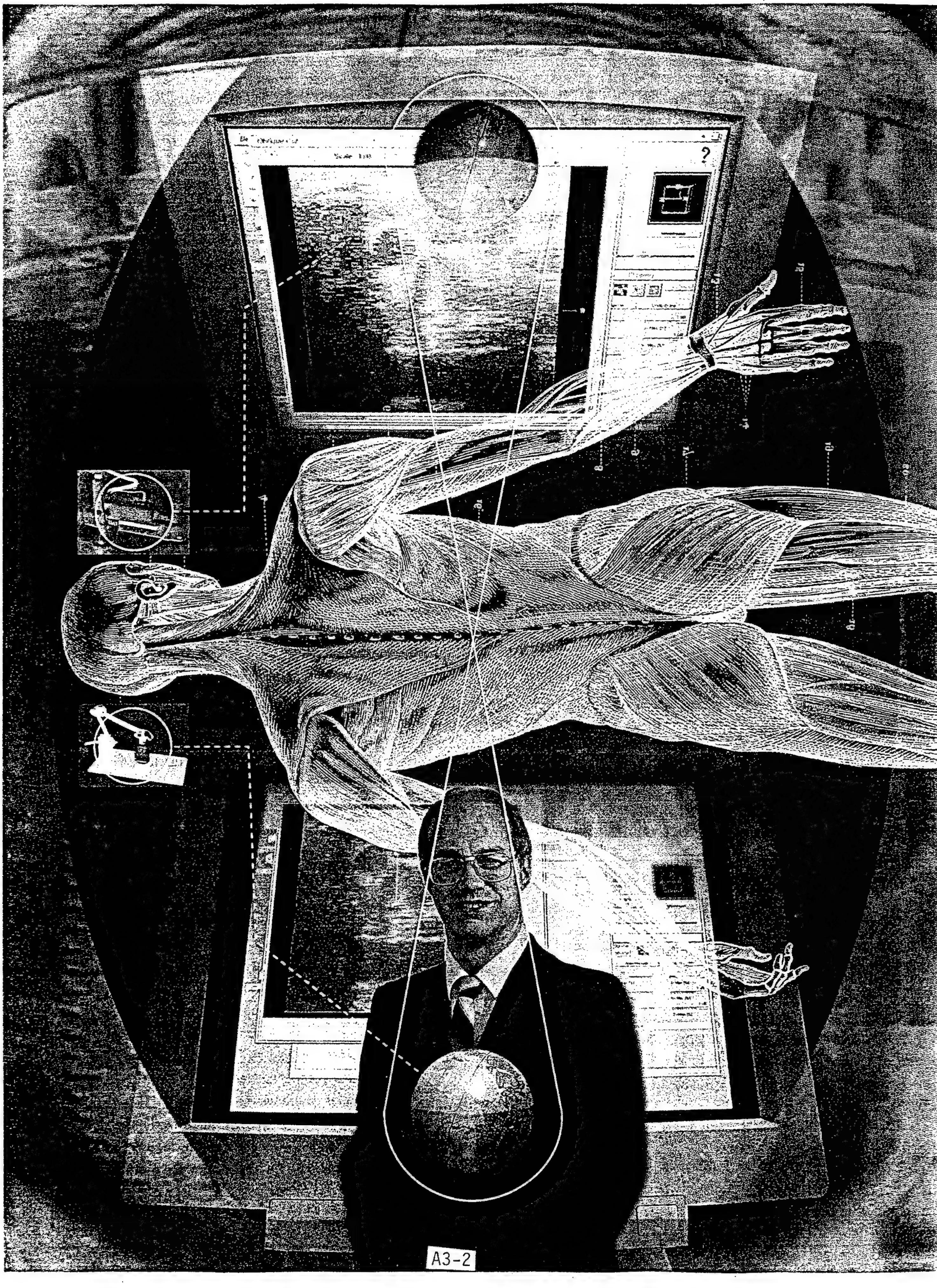
(d) an on-site computer having software instructions that combines the plurality of 2-D reflected image signals into a volumized data set, said first computer further having a communication link for transmitting the volumized data set to the diagnostic computer.

7. The apparatus as recited in claim 6, wherein the software instructions comprise a video capture and volumization software that receives the plurality of 2-D reflected image signals as a plurality of frames, each of the plurality of frames volumized with respect to adjacent frames to produce the volumized data set.

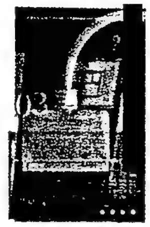
8. The apparatus as recited in claim 7, wherein the software instructions further comprise a 3-D visualization software that receives the volumized data set and produces a 3-D visualization data set.


SPECIAL EPCOT EDITION: INNOVATORS OF THE FUTURE
Discover
THE WORLD OF SCIENCE
July 1997
8TH ANNUAL
TECHNOLOGY
AWARDS

A3-1



A3-2



Ultra Ultrasound

Winner: Pacific Northwest National Laboratory's Portable Ultrasound Unit

Innovator: Rik Littlefield

IMAGINE A DOCTOR IN NEW YORK examining a wounded soldier in Bosnia with ultrasound. All the technology needed to perform such a feat—portable ultrasound devices and the means for transmitting the data from them—are available right now. There's just one problem, says Rik Littlefield—most doctors wouldn't know how to use the equipment. To sift through transmitted images displayed on a monitor, the doctor in New York would have to master arcane computer keyboard and mouse commands. "It's nonintuitive and ineffective," he says. "Most doctors just wouldn't bother to learn how."

Littlefield, a computer scientist at Pacific Northwest National Laboratory in Richland, Washington, has put together a portable ultrasound system that makes the doctor in New York feel as though he is actually on the battlefield. The field operator—who requires only a modest amount of training—positions a probe over the patient's wound and then the system mechanically scans inside the patient. The 3-D data are then transmitted to a computer back at the hospital. There the doctor holds an input device that looks and feels like the handheld probes that doctors ordinarily use on ultrasound patients. As the doctor moves and twists the ersatz probe in midair, motion-tracking sensors relay positioning data to the computer, which responds by changing the view on the doctor's screen as though the patient were lying there in front of him. "Of the two dozen doctors who have tried it," says Littlefield, "not one has taken more than five minutes to get comfortable enough to make a diagnosis. The old system took me hours to learn, and I'm supposed to be an expert."

Littlefield had a prototype tested last August, and now he is readying a final unit to submit to the U.S. Food and Drug Administration for approval. Although the military will probably make the first units for the battlefield, rural health care is likely to benefit as costs come down in a few years. "I've already started getting calls from doctors in Alaskan bush communities and from Native American reservations," says Littlefield.

information—about as much as you'd find on the typical business card. Last year, now as a researcher at IBM's Almaden Research Center in San Jose, California, he added some security features and made it small enough to fit in a pocket. "I want to replace all the cards you have in your wallet with this one device," he says.

Unlike the free-flowing electrons of an electric current, the static electric field

Original portrait photograph by Jan Jackson; original product photographs by Walter Calahan

PHOTO ILLUSTRATIONS BY STUART BRADFORD

A3-3

Appendix 4:

"Ultrasound marches to the front", Portable Design Magazine cover article, June 1997

Ultrasound marches to the front

John H. Mayer, Contributing Editor

In military medical care, it's axiomatic that what happens during the golden hour—the 60 minutes immediately following a serious wound or injury—is key to patient survival. Unfortunately, sophisticated diagnostic equipment, crucial to treat life-threatening wounds swiftly, has been too cumbersome to take into the field, and the golden hour often passes—along with the casualty. What's needed is better portable medical gear.

A multidisciplinary design team uses off-the-shelf subsystems to rapidly develop a portable telemedicine box.

Now, a joint effort by researchers at Pacific Northwest National Laboratory (Richland, Wash.) changes the portable picture. Working with medical technology experts at the Defense Advanced Research Projects Agency (DARPA) and designers at the U.S. Army Medical Research and Materiel Command, a design team has developed just such a system—a portable ultrasound imager. It's purpose is to bring the benefits of sophisticated ultrasound imaging—conventionally used in hospitals—to the front lines in combat situations.

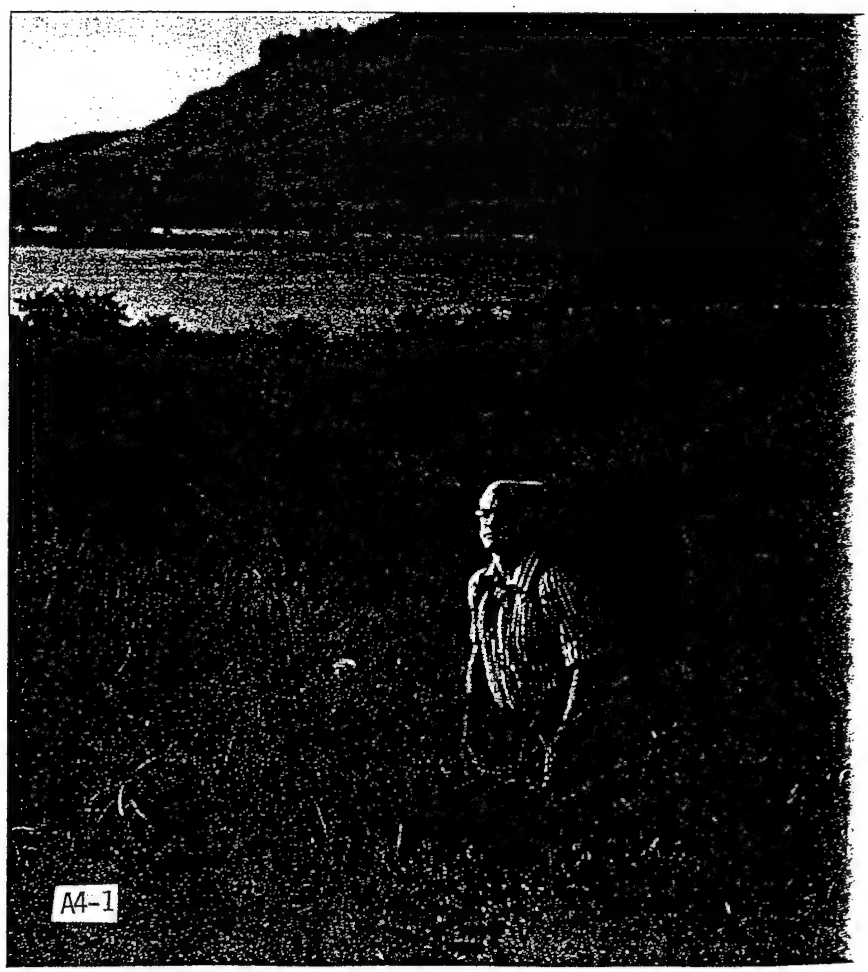
Commercial potential

Promising to someday reduce the number of battlefield deaths, while offering tremendous commercial potential, the joint design effort resulted in the design of what's called a Medical Ultrasound, Three-dimensional and Portable with Advanced Communications box (any GI will tell you it's easier to call it by its acronym: MUSTPAC-1).

"If a patient's bleeding in the field or, for that matter, in some remote county in West Virginia, I don't have time to take him to an MRI," says Dr. Christian Macedonia, principal medical investigator on the project. "The direction medical diagnostics has to go is toward making systems that are lightweight and portable in design so you can take them to the patient." Macedonia is also a major with the U.S. Army Medical Corps at Georgetown University Medical Center, so he knows of what he speaks.

Ease of use is key

The MUSTPAC-1 permits a semiskilled operator to perform 3-D scans of an injured soldier and send those images for interpretation to experts anywhere in the world. Macedonia is credited with much of the initial vision for MUSTPAC. In fact, he began exploring the use of 3-D ultrasound while he was a medical student in the early 1990s.



A4-1

At that time, Macedonia was interested in exploring how different chest ventilation methods affected blood flow throughout the body. While he uncovered significant research on Doppler ultrasound, one of his criticisms was that it couldn't be used to track moving objects. "It occurred to me that we have radar systems that can track missiles in flight, so why can't we apply some defense technology toward this problem?"

It took a few years, but Macedonia eventually hacked together a prototype that embodied his ideas. Using off-the-shelf components, he pieced together a Macintosh 7100 computer, a trackball keyboard, and an ultrasound machine. He used a scan converter to transform the Macintosh video output to NTSC video and then ran it back out the monitor of the ultrasound machine. Did it work? "Yes," tells Macedonia, "but it generated images that were nice to look at, but weren't particularly useful."

Knowing he'd reached his technical limits, Macedonia took his idea to developers at Pacific Northwest National Laboratory, operated by Battelle for the U.S. Department of Energy (DOE). Shortly thereafter, the DOE and the Department of Defense (through DARPA) agreed to put up $5 million to develop a 3-D ultrasound system for diagnosing battlefield injuries.

A MUSTPAC must

While conventional ultrasound is a 2-D imaging procedure, 3-D ultrasound was critical to the premise behind MUSTPAC—scanning a fairly large volume of the patient at a remote site by an unskilled operator and then transferring the data in a store-and-forward file transfer mode to a skilled diagnostician.

"The point of the 3-D is that it permits data to be collected by someone who knows a little anatomy, but doesn't know anything about how to interpret ultrasound images," explains Rik Littlefield, project manager at Pacific Northwest National Laboratory.

Littlefield notes that a classic ultrasound exam is performed by a technician viewing a real-time, 15-frame/sec image as he moves a probe around the body. Without that ability and without the knowledge of how to interpret those images and where to re-point his hand to see what he really needs to see, the operator can't perform the exam.

"What 3-D data collection permits is to collect perfectly useful data in a sort of blind snapshot mode," says Littlefield. "If you think someone might have a gallstone, obviously the person who collects the data has to know where the gall bladder is. But he doesn't have to know what angle to point the probe in order to image the duct at the right angle to take the measurements."

In the MUSTPAC, a specially-designed simulated probe looks, feels, and acts like a real ultrasound probe. Littlefield adds that once an image is stored in a 3-D dataset, it can later be reviewed either locally or remotely.

Fourth of July prototyping

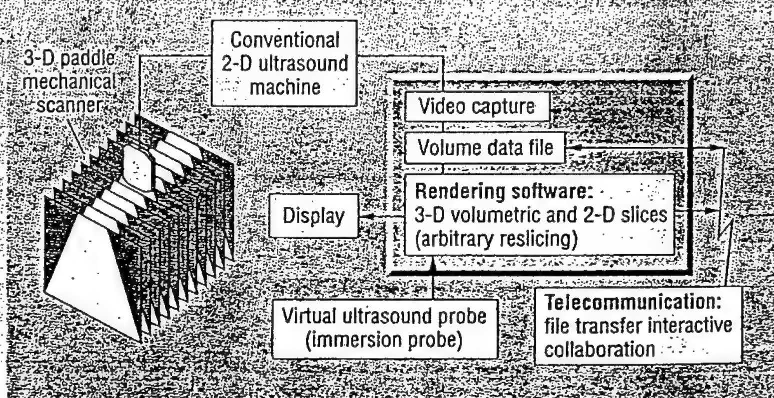
Once funding was approved for the project (that happened in April of 1996), development of the MUSTPAC proceeded at what had to be a rapid pace. Driving the team was a schedule that called for delivery of a prototype by early July.

Much like Macedonia's original design, MUSTPAC-1 designers built the unit around off-the-shelf components. The team also imposed a requirement that the system be transportable by a single soldier. "As an officer in the First Infantry Division in Germany, I clearly remember that the most useful equipment was that which one person could carry," notes Macedonia. "If it's small enough, it can go practically anywhere."

Anatomy of a telemedicine box

In its 85-pound backpack configuration, the first-generation MUSTPAC-1 supplies what's needed to acquire 3-D ultrasound data, visualize it locally, and transmit the data to a remote site for consultation in a teleconference. The MUSTPAC-1 is powered from a commercial uninterruptible power supply, using a battery, for about 45 minutes. It can also be powered from an ac line. The core of the system is a Hitachi Medical Systems Model EUB-905 2-D ultrasound subsystem.

The EUB-905 links to a Silicon Graphics Indy workstation by means of a 75-ohm video cable. Video-capture software feeds a 3-D dataset into a volume data file residing on the Indy's hard disk. Rendering software then permits operators to arbitrarily re-slice the 3-D dataset at any position or orientation using a stand-alone, joysticklike virtual ultrasound probe. Data is transferred to remote sites via a standard Ethernet connection. A stand-alone camera supports videoconferencing.



It was decided to make the system fit into a backpack. "That meant it clearly had to be under 100 pounds," recalls Littlefield. What the team ultimately designed weighed in at 85 pounds.

Close to 25 pounds of the total weight was attributable to the centerpiece of the system, an off-the-shelf EUB-905 ultrasound subsystem from Hitachi Medical Systems (Tarrytown, N.Y.). Measuring 13.6 × 16 × 6.4 inches in size (34 × 40 × 16 cm) the compact 2-D unit offered a variety of display modes, as well as 192 channel probes, 256 gray-scale steps, and a high-frequency probe that operates at up to 10 MHz. It can also be powered off either a 120-V ac line or batteries.

"We picked the EUB-905 because it offered an excellent combination of image quality

"A Pentium portable with integrated keyboard will likely eliminate the bulk of the stand-alone keyboard"

and size and weight," explains Littlefield. Also important to the selection of the EUB-905 was that it had won Food and Drug Administration FDA 510(k) approval.

With future commercialization on their minds, MUSTPAC designers went out of their way to avoid customizing the subsystem. "We avoided like the plague breaking into that system," explains Littlefield. "Doing anything at all to it that could affect its performance would have voided the 510(k) approval."

Complementing the EUB-905 is a 3-D paddle electromechanical scanner. Compact and lightweight, the paddle was designed to be strong enough to support several pounds of longitudinal thrust and withstand pushing against a patient's body.

Weight versus Mips

The second heaviest component in the MUSTPAC-1 is its compute platform. For that element, the design team chose an Indy workstation from Silicon Graphics Inc. (SGI—Mountain View, Calif.). Built around a 64-bit MIPS R5000 microprocessor, the SGI workstation is optimized for compute-intensive

"3-D permits data to be collected by someone who knows a little anatomy, but doesn't know anything about how to interpret ultrasound images," explains Rik Littlefield, project manager at Pacific Northwest National Laboratory.

graphics and multimedia applications. The MUSTPAC design team picked a platform with a 2-Gbyte hard drive and support for seven SCSI-2 devices. The team then loaded it with 128 Mbytes of RAM to minimize disk accesses.

While bulkier than currently available laptops, the Indy was deemed a clear choice for MUSTPAC, as it offered video-capture capabilities in a Unix environment. "We were considering some Pentium-based notebooks, but there was no way we were going to get the quality video capture we needed within the time frame we needed it," notes Littlefield. "What's more, since our visualization software already ran in Unix, we didn't have to do a port to Windows NT."

There were tradeoffs. One of the drawbacks to the Indy platform was that it required a stand-alone keyboard. "In theory, we could've done the whole thing with a touch panel," says Littlefield. "But we knew the users we were targeting wanted not just a 3-D ultrasound system, but a more general-purpose platform." For future-generation MUSTPACs, Littlefield indicates a Pentium portable with integrated keyboard will likely eliminate the bulk of the stand-alone keyboard.

Since the Indy doesn't come with an integrated display, the MUSTPAC designers opted to add an SGI presenter panel to the backpack configuration. "We needed 1,024 × 1,280-pixel resolution with CRT-quality gray scale," explains Littlefield. "Physicians performing diagnosis at remote locations use a standard analog CRT."

Image objections

"A common gripe among doctors about ultrasound-captured static images is you can't tell what you're looking at unless somebody tells you where the probe was pointed," explains Littlefield. "A standard joke is you can't tell the difference between an ovarian cyst and a gall bladder."

A problem for the MUSTPAC designers was the realization that trained ultrasound diagnosticians were used to working in a 2-D environment, not with a 3-D dataset. "Through years of training, doctors have developed great amounts of skill and hand-eye coordination in terms of being able to infer 3-D anatomy—based not only on where they think their hand is pointing right now, but also how an image changes as they move their hand," says Littlefield.

"Since the person doing the diagnosis wasn't going to be physically located with the patient, and wouldn't have direct control over the imaging," continues Littlefield, "we felt it was very important to give the operators a familiar interface that would permit them to exploit all their standard skills."

"It's kind of counter-intuitive," adds Macedonia. "People who aren't in medicine typically think, 'Gosh, it seems like a 3-D image would be a lot more useful than a 2-D image.' But the fact of the matter is that the experienced radiologist uses a 2-D image and does 3-D reconstruction in his or her head."

One answer to the visualization problem was sitting just down the hall in Littlefield's office. "One day I was mulling over how to solve this problem and I happened to walk through our multimedia lab," he remembers. "Sitting on the table was a fancy joystick, with XYZ pitch, roll, and yaw. What more natural thing to do than to simply let the software listen to that device and put the corresponding images up on the screen? We'll fake a real-time examination, I thought."

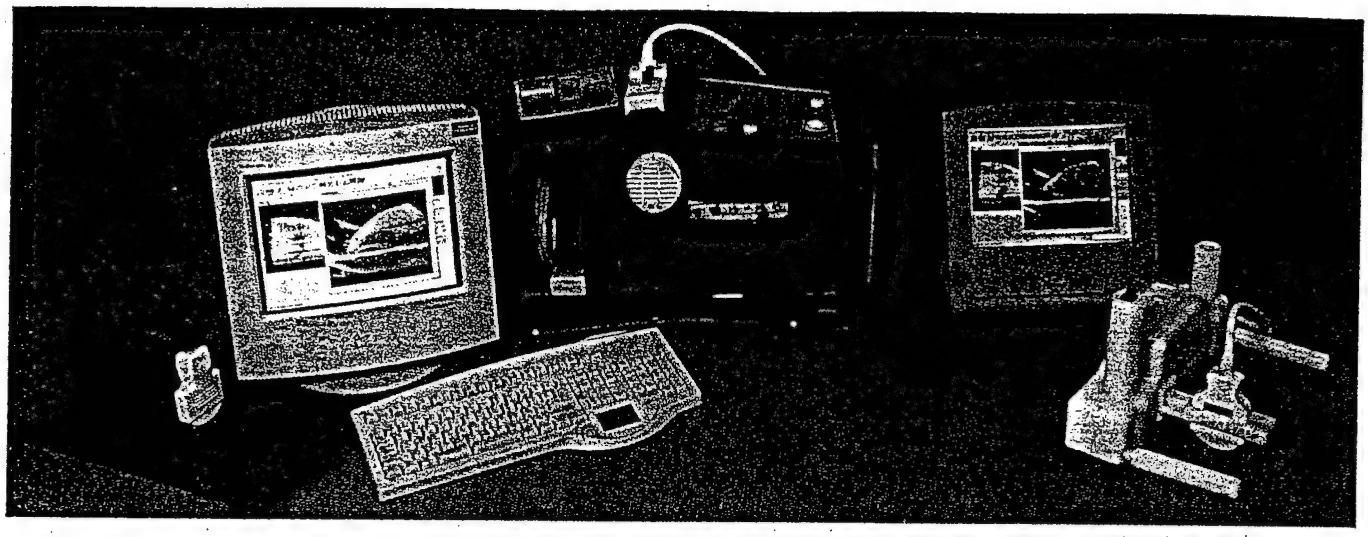
Out of that idea came a virtual ultrasound, or immersion, probe. Offering equivalent 6-D sensing capability (3-D position plus 2-D tilt and rotation), the probe—with the help of special volume-visualization software—can be used to re-slice the ultrasound information along arbitrary so-called cutting planes.

Software ain't easy

While the MUSTPAC-1 development project relied largely on off-the-shelf components to minimize design time, software was another story. Much of the innovative integration work for the MUSTPAC came about in software development.

The Fraunhofer Center for Research in Computer Graphics (CRCG—Providence, R.I.) played a key role. It's a non-profit computer graphics research group specializing in the study of volume visualizations, virtual environments, collaborative work tools, and user interfaces.

Researchers at the center modified TeleInViVo, 3-D ultrasound visualization software based on InViVo 3-D volume-visualization code developed by Dr. Georgios Sakas at the institute's Darmstadt, Germany, facility. Featuring network collaboration tools for remote consultation and system control, TeleInViVo permits physicians to view a range of data sets, including CAT (computer-assisted tomography), MRI (magnetic resonance imaging), MRA (magnetic resonance angiography), and PET (positron emission tomography) scans. It also allows users to exchange and manipulate the data sets via ISDN or ATM net-



Weighing about 85 pounds, the MUSTPAC-1 includes an ultrasound system, a 3-D paddle, and a large LCD screen. A Silicon Graphics workstation-class Indy computer—with camera—completes the picture.

works. CRCG made modifications of the software to enable the use of the virtual ultrasound probe.

CRCG's software used position and orientation information derived by the probe to re-slice the 3-D ultrasound data along arbitrary cutting planes. The screen image is updated in real time so that diagnosticians see the 3-D MUSTPAC scans as conventional 2-D images.

GUI anxiety

Concurrently with hardware and TeleInViVo integration, programmers at Pacific Northwest National Laboratory also wrote code to bring the system's components together. One of the more challenging aspects of this was writing video-capture software and a graphical user interface. "Making it run acceptably fast was an ongoing exercise in frustration," admits Littlefield.

For the video input side, MUSTPAC designers built their applications on top of VL, a library from SGI. But since VL didn't handle any functions on the output side, the team's programmers had to write custom code to glue the VL-based applications with the user interface. The latter was written in TCL, a language and support library that comes out of the X Windows world.

While the actual amount of code proved relatively small, the task of managing the video input, as well as handing off the imagery to TCL for display on the screen and as a backdrop for the user interface, proved to be a very difficult task. "TCL is designed to use an event loop philosophy; it provides an event handler of its own," Littlefield explains. "SGI's VL is also designed to use the event-loop philosophy, but it uses an event loop of its own. Getting those two glued together so that all the events on both video input and X Windows sides were properly interleaved turned into a matter of several weeks of hair tearing."

No batteries included

Power-supply issues were also critical. At first, operating power was not a concern for the design team. Intended for use in armed forces Mobile Army Surgical Hospital (MASH) units, the MUSTPAC-1 was initially designed to operate from a standard 120-V ac power line. However, in the interest of making the unit truly useful in combat, the system also needed a battery-powered option. It was supplied with an off-the-shelf, 30-lb uninterruptible power supply. "The MUSTPAC is sufficiently low power that we could get 45 minutes of continuous operation off a standard UPS system," says Littlefield.

Similarly, the system's communications options were significantly narrowed when initial requirements called for its use with established Signal Corps connections. "They said, 'Look, we'll just give you a 10Base-T connection talking TCP/IP.' We said, 'Great,'" retells Littlefield. But down the road, Littlefield's designers still see an opportunity—particularly if the system is brought to commercialization. They want to add RF wireless capability in future iterations of the design. Littlefield sees RF satellite links, such as those based on the Immarsat birds, as the most likely scenario for this. Dual-mode cellphone technology is also feasible, he says.

Tuzla-tested

The MUSTPAC-1 prototype was shipped in July of 1996, but its first real-world trial came a month later when Macedonia took the system to the 212th MASH at Camp Bedrock in Tuzla, Bosnia. Concerns about reliability were quickly put to rest when Macedonia went to unload the system after it took a truck ride down a seven mile road called Crater Alley. To his dismay, Macedonia found the system had bounced off its palette and was lying in a corner of the back of the truck. "It had the crap kicked out of it," he unabashedly declares.

But the unit didn't fail. Once set up at MASH headquarters, the system was fired up and linked to the Army's local 10base-T Ethernet network. Data was transmitted back through a microwave link to a base miles away and then fed through a Ku-band

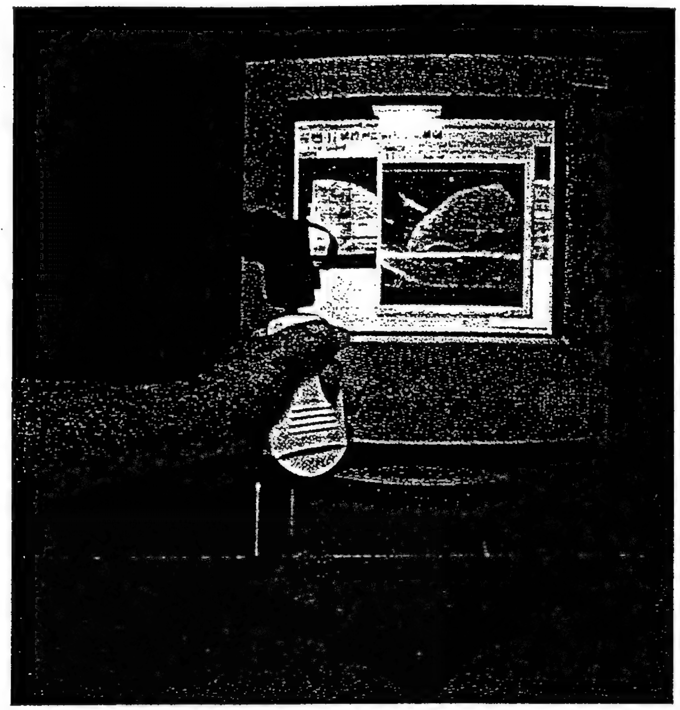
satellite link to another MUSTPAC unit in Landstuhl, Germany. That field test proved clearly that data could be collected and transmitted by personnel inexperienced with ultrasound technology.

"I initially thought I was going have to do all the scans," recalls Macedonia. "But when I got there, everyone asked to try it. Eventually, we had a medic, a Russian nurse, and even a chaplain try it out." The ability of diagnosticians to use the virtual ultrasound probe also exceeded expectations. "It became very clear it didn't matter who was doing a scan," recounts Macedonia.

Some of the results of the trip were completely unexpected. "We went into Bosnia thinking we were taking in a 3-D ultrasound machine and came out of the experience realizing we had what could be called a portable telemedicine system—that at its core had ultrasound," avows Macedonia.

Since the system does frame capture, users at the MASH quickly began experimenting with CCD cameras and other instruments to capture eye exams, ear exams, and even dental exams. They were anxious to send them in a store-and-forward fashion back to the rear. "The people at the MASH taught us that it's really a portable telemedicine system that allows you to examine a patient from the top of their head to bottom of their feet," jocularly notes Macedonia.

Users with little ultrasound training can collect data for remote analysis using the MUSTPAC-1 backpack telemedicine system.



A lighter future

At the moment, the MUSTPAC design team is focusing on reducing system weight and cost; a new-generation system is in the works. Key to achieving the goal will be a migration to a lighter and more compact Pentium-based platform that will include keyboard, display, and processor in a single unit. "That should eliminate about 10 pounds," believes Littlefield. "It'll eliminate a bunch of cable and separable interconnect problems as well."

"The development's a continuous evolution," concludes Macedonia. "I don't see an end to the MUSTPAC-1 project until we create a handheld—not a backpack—that allows me to have a look at people's bodies and figure out what's going on inside."

For more information...

Battelle/Pacific Northwest National Laboratory
Richland, WA
(509) 375-3776
Circle 155

Hitachi Medical Systems
Tarrytown, NY
(914) 524-9711
Circle 156

Silicon Graphics
Mountain View, CA
(408) 960-1980
Circle 157

The Fraunhofer Center for Research in Computer Graphics
Providence, RI
(401) 454-7490
Circle 158

A4-6

Appendix 5:

"Backpack remote medicine proves its worth", Janes International Defense Review, February 1997

Backpack remote medicine proves its worth

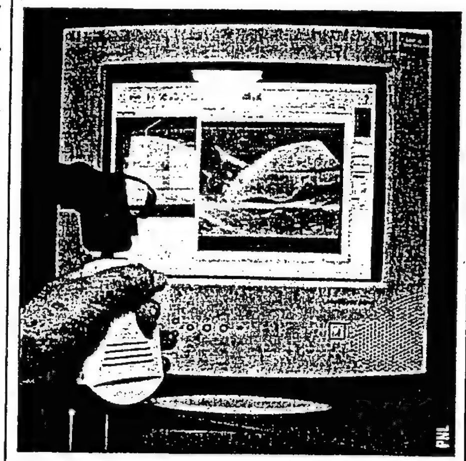
A portable telemedicine system providing ultrasound facilities for use in field hospitals has undergone successful trials with the US Army in Bosnia. Pacific Northwest Laboratory (PNL) developed the Medical UltraSound, Three-dimensional and Portable with Advanced Communication (MUSTPAC) system under a rapid-prototyping contract from the US Defense Advanced Research Projects Agency. The design exploits existing technology to make referral and diagnosis easier in the field, leading to improved patient care and a reduction in the number of unnecessary evacuations.

PNL says that MUSTPAC is unique in that it is effective, requires very little training, does not need a highly skilled operator at the patient's side, and operates well even in a low-bandwidth store-and-forward file-transfer mode. The laboratory is developing a production-standard version that is lighter, more compact, and uses different computer hardware.

MUSTPAC consists of a field unit installed in a backpack, allowing it to be operated as far forward as battalion aid stations, together with a separate virtual ultrasound probe and high-resolution color monitor. In its prototype form, the backpack contains a 'three-dimensional [3-D] paddle' electromechanical scanner; Silicon Graphics Presenter flat-panel display; Hitachi EUB-905 ultrasound machine; Silicon Graphics Indy computer; teleconferencing video camera; and keyboard with integral touchpad. The separate Immersion Probe — a virtual ultrasound probe — provides expert diagnosticians with a familiar interface that is easy to learn and to use.

The system permits on-the-spot visualization of internal bleeding, damage to solid organs, and penetrating injuries. It operates by scanning a fairly large volume of the patient at one time, so that diagnosis during the scan is not required. The operator places the scanner on the patient's abdomen for about 10s, while the system acquires a large volume of 3-D data. This requires minimal training. US Marine Corps Capt (now Maj) Christian Macedonia, the MUSTPAC Principal Medical Investigator, talked a Russian nurse through the process, via an interpreter, in about 5min during trials in Bosnia.

The equipment also provides a remote diagnostician with a familiar interface. The 'virtual ultrasound probe' consists of a modified Immersion Probe or an equivalent 6-D sensing capability (3-D position, 2-D tilt, and rotation). TeleInViVo visualization software developed by the Fraunhofer Center for Research in Computer Graphics uses probe position and orientation inputs to 'reslice' the 3-D ultrasound data along arbitrary cutting planes. The screen view is updated in real time (5–10 times a second), so that diagnosticians can work with MUSTPAC 3-D scans in the same way that they would with a real patient and a conventional 2-D ultrasound system.



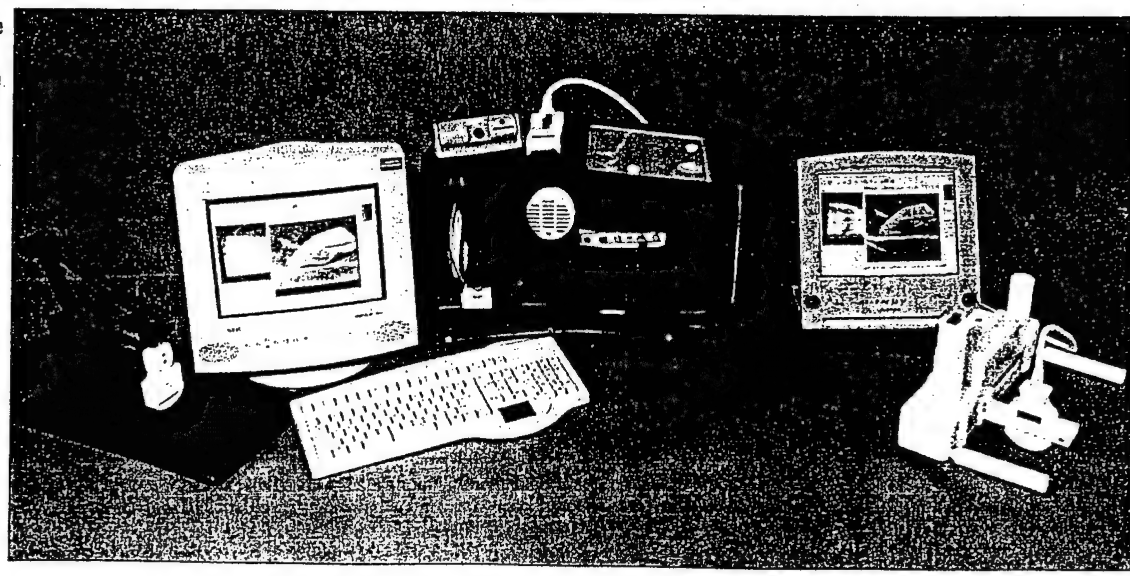
Consulting physicians on another continent can use MUSTPAC's virtual-reality technology to obtain 2-D diagnostic views from 3-D ultrasound data. An Immersion Probe provides high-resolution pictures of scans taken elsewhere.

PNL delivered the MUSTPAC-1 prototype to the US Army Medical Research and Materiel Command's Medical Advanced Technology Management Office in July last year. Following a series of pre-deployment evaluations supervised by the Center for Total Access at Fort Gordon, it was shipped to Landstuhl in Germany. In early August the equipment began a month-long deployment with the 212th Mobile Army Surgical Hospital at Camp Bedrock in Tuzla, Bosnia. It transmitted data through a microwave link to Eagle Base, 12km away, and then fed through a Ku-band satellite link to another MUSTPAC unit in Landstuhl. Four other receiving sites were situated in the US.

The MUSTPAC-1 prototype weighs just under 40kg. The production-standard version now under development will be more compact, weigh about 27kg, and incorporate a laptop computer in place of the Indy unit. The equipment may then enter limited production under a government/industry partnership. Potential users include rapid-reaction forces and naval units.

In the latter case, MUSTPAC could assist in detecting gallstones, diagnosing kidney disease, and meeting the need for gynecological care that has resulted from the deployment of women aboard warships. The system could also form an adjunct to image-directed surgery for immediate treatment. MUSTPAC could show the position of both injuries and surgical instruments, supporting tasks such as the injection of glue to stitch internal wounds. **MH**

The MUSTPAC-1 prototype consists of a virtual ultrasound probe (extreme left of photograph), high-resolution color monitor (next to the probe), and a backpack (center) containing the other elements. These comprise an electromechanical scanner (extreme right), flat-panel display (next to it), ultrasound machine and its associated computer (both in backpack), teleconferencing camera (on backpack), and keyboard with integral touchpad (foreground).



Appendix 6:

Presentation to MUSTPAC-2 Expert Review Panel,

August 5, 1997

MUSTPAC Objective

Develop and make available for routine use
an effective ultrasound telemedicine system
that does not require diagnostic skills
at the patient's location.

Design Philosophy

- Evolutionary development
- Alternating advances in hardware and software

MUSTPAC-1 (4Q1996)

- Investigational device, IRB approval
- 85-pound backpack
- Data acquisition via motor-driven linear device (1st generation)
- B-mode only
- Manufacturing and support capability: none in place
- Rapid prototype assembly incorporating:
  - small desktop computer (SGI Indy)
  - separate flat panel display and keyboard
  - separately packaged ultrasound system (Hitachi EUB-905)
  - user interface split between computer and ultrasound system
- Irix (SGI Unix) operating system plus Windows applications
- TCP/IP communications, no encryption

MUSTPAC-2 (4Q1998)

- FDA 510(k) approved
- 65-pound wheeled case
- Data acquisition via two mechanisms
  - primary: motor-driven linear scan device (2nd generation)
  - secondary: freehand scanning (via magnetic position sensor)
- B-mode only
- Manufacturing and support capability: target 50 units, $100K/unit
- Modest level of integration incorporating:
  - laptop style computer subsystem
  - separately packaged ultrasound system (Hitachi EUB-905)
  - user interface split between computer and ultrasound system
- Windows/NT operating system
- TCP/IP communications, encryption provided

MUSTPAC-2 (Interim - 4Q1997)

- ➡ Investigational device, initial 510(k) application submitted
- ◆ 65-pound wheeled case
- ➡ Data acquisition via one mechanism
  - primary: motor-driven linear scan device (2nd generation)
- ◆ B-mode only
- ➡ Manufacturing and support capability: developing
- ◆ Modest level of integration incorporating:
  - laptop style computer subsystem
  - separately packaged ultrasound system (Hitachi EUB-905)
  - user interface split between computer and ultrasound system
- ➡ Solaris operating system plus Windows applications
- ◆ TCP/IP communications, encryption provided

➡ (indicates difference from 4Q1998 version)

MUSTPAC-3 (4Q 2000)

- ◆ 25-pound briefcase
- ◆ Multiple ultrasound modes:
  - B-mode
  - Doppler power angio
  - motion capture and display
- ◆ Data acquisition via three mechanisms
  - primary: freehand scanning (magnetic free space sensor)
  - optional: 3-D paddle (motor-driven linear scan device)
  - optional: motion capture via slow linear scan
- ◆ Designed for civilian as well as military use
- ◆ Manufacturing and support capability: target 500 units, $30K/unit
- ◆ Highly integrated system incorporating
  - board-level ultrasound subsystem
  - low cost OEM-type computer subsystem
  - single user interface (ultrasound subsystem controlled by computer)

Clinical Study

- Georgetown University Medical Center
- Title: *Reformatting of three-dimensional ultrasound data sets for remote consultation: Are fetal anomalies detectable and are biometric measurements accurate in 3D Ultrasound data sets*
- 60 patients: 20 known anomalies, 40 normal
- 2-D and 3-D scans archived, blind comparison of interpretation and biometric measurements

Independent Publications

- Jane's International Defense Review, Feb.1997
- Portable Design Magazine, June 1997 (cover article)

Honors

- Discover Award Winner, June 1997 (Discover Magazine) Computer Hardware and Electronics
- Solution of the Year, June 1997 (Advanced Imaging Magazine), Scientific Visualization

Press Coverage

- Associated Press - numerous articles
- Broadcast TV (CBS, CNBC, Discovery Channel)

Invited Presentations

- AUSA annual meeting
- AUSA Telemedicine Conference
- Military Medical Capabilities Conference
- Society of Minimally Invasive Theraputics (Japan)
- Spanish Society of OB/GYN (Spain)
- Tribal Healthcare 2000 Conference
- AMEDD Conference on Force Structure and Requirements in Telemedicine
- ... and others ...

Appendix 7:

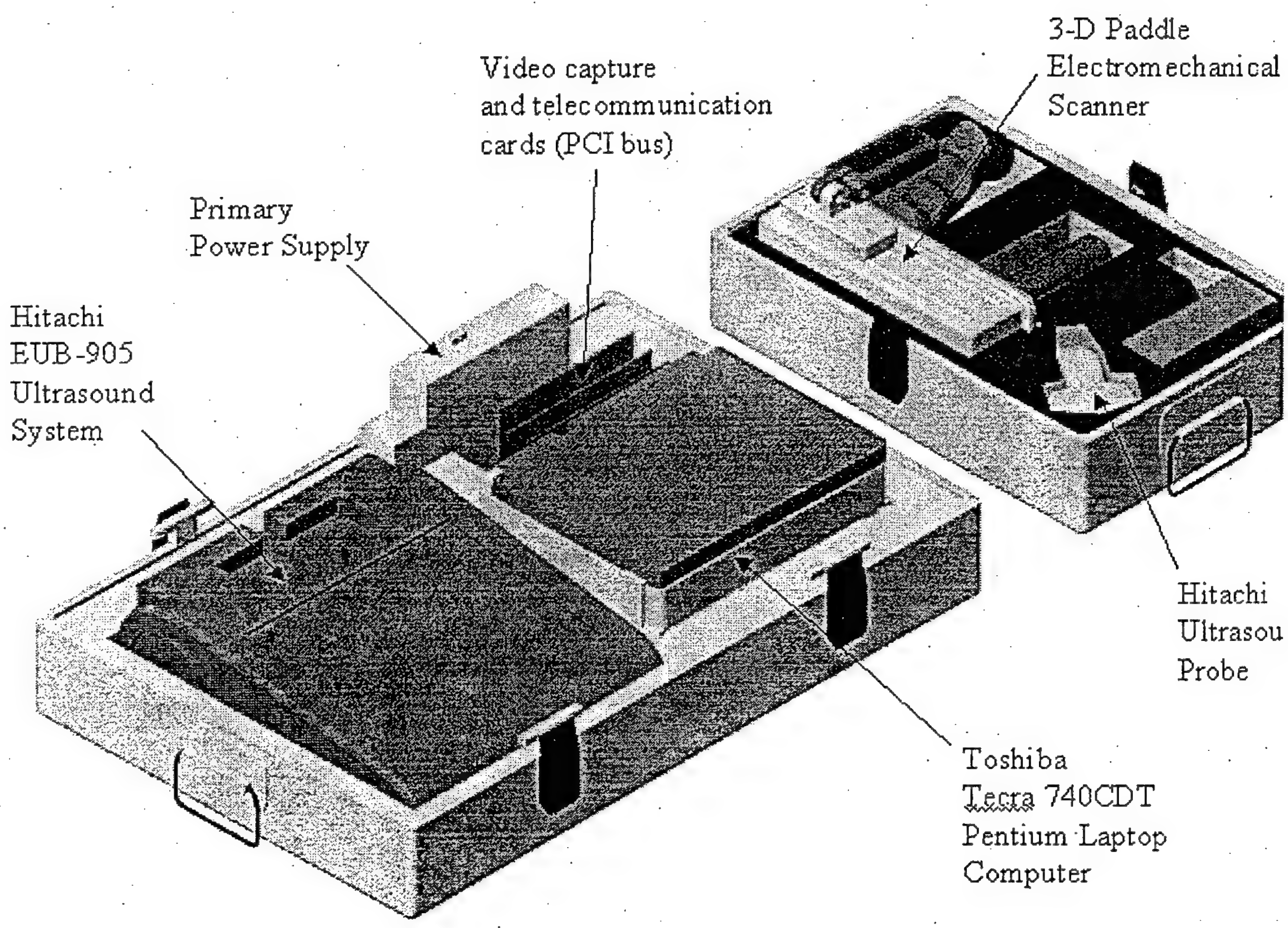
MUSTPAC-2 Prototype, 10/15/97

MUSTPAC-2 Prototype, 10/15/97

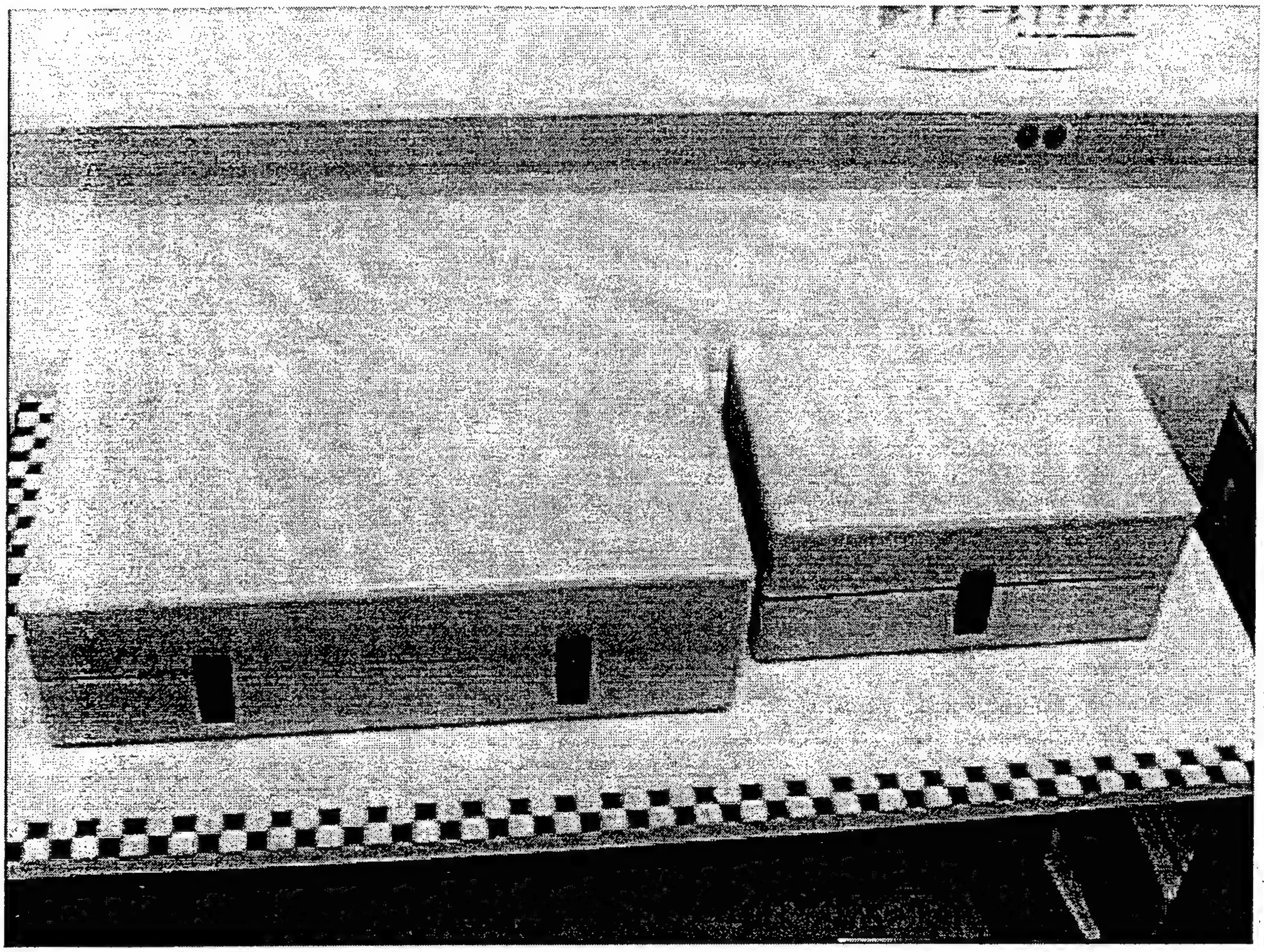
Background

MUSTPAC (**M**edical **U**ltraSound, **T**hree-dimensional and **P**ortable, with **A**dvanced **C**ommunications) is a telemedicine system that uses 3-D ultrasound data acquisition. It provides the unique capability of allowing an effective ultrasound examination to be performed without requiring ultrasound diagnostic skills at the patient's location. The MUSTPAC-2 system is a successor to the highly regarded MUSTPAC-1 and operates on similar principles. System design and field experiences of the MUSTPAC-1 are described in an accompanying report, "MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater". An earlier description of the MUSTPAC-1, dated 12/96, is also available

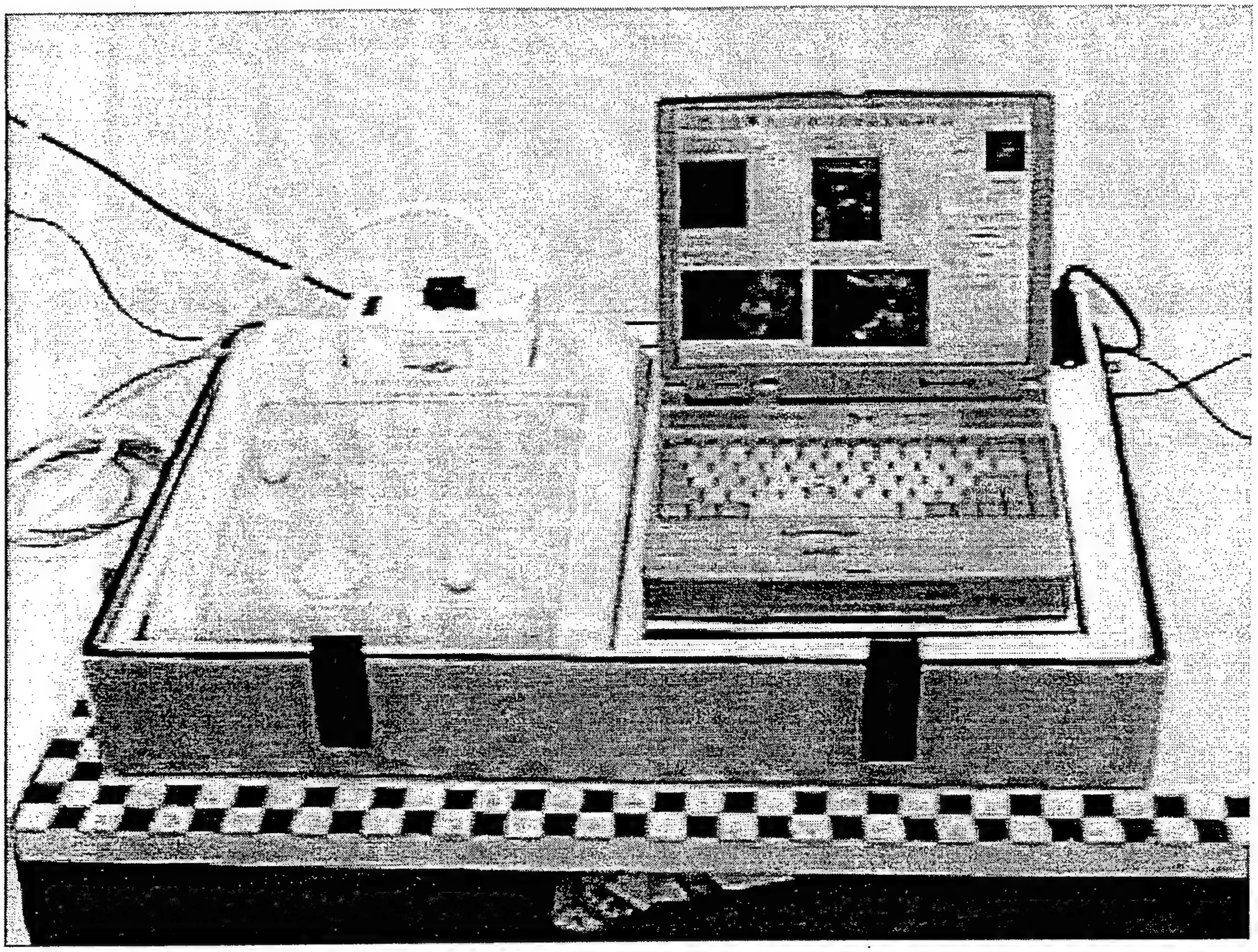
Following are pictures of the MUSTPAC-2 prototype system, taken during a system integration test on October 15, 1997.



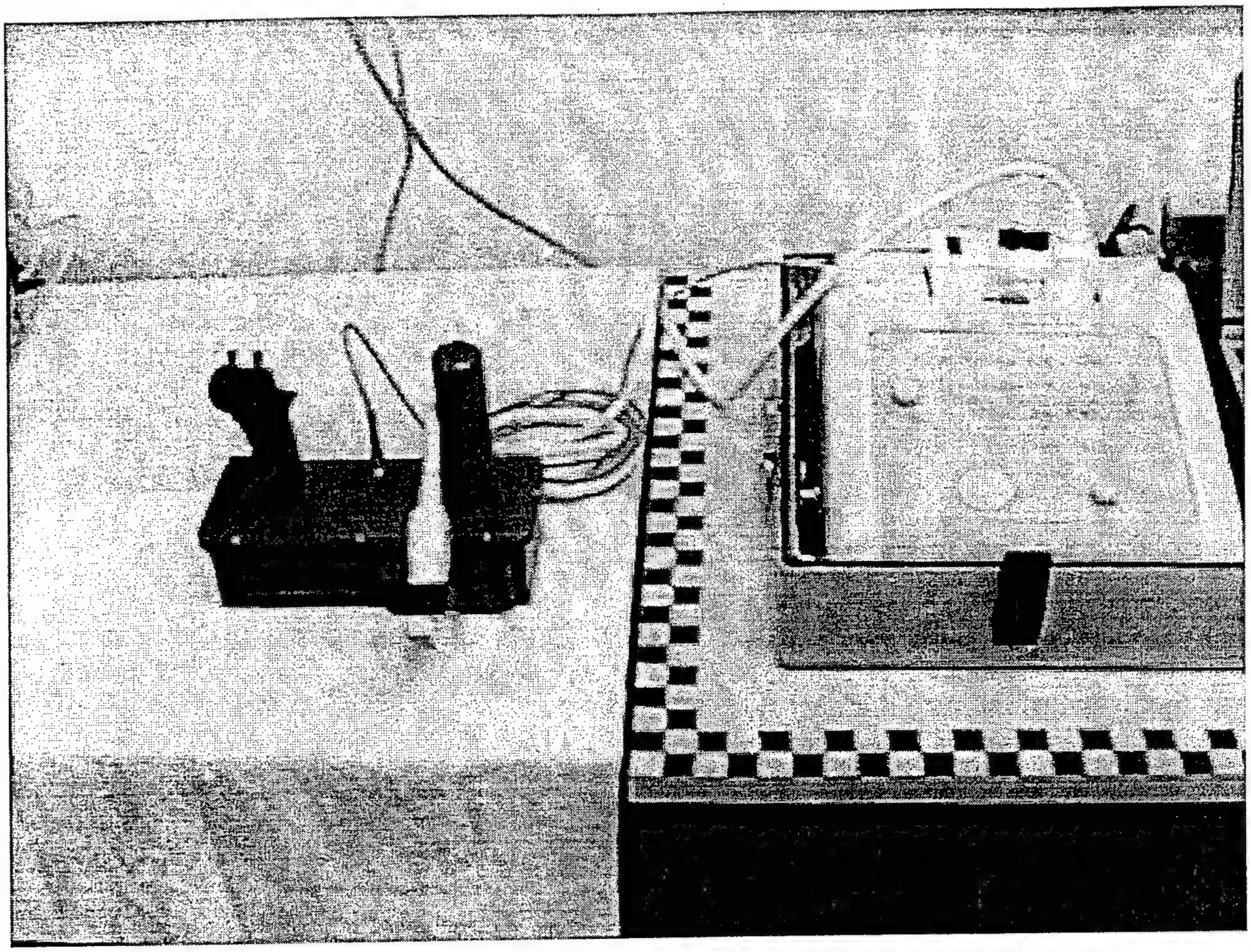
SolidWorks CAD drawing of module and case layout.



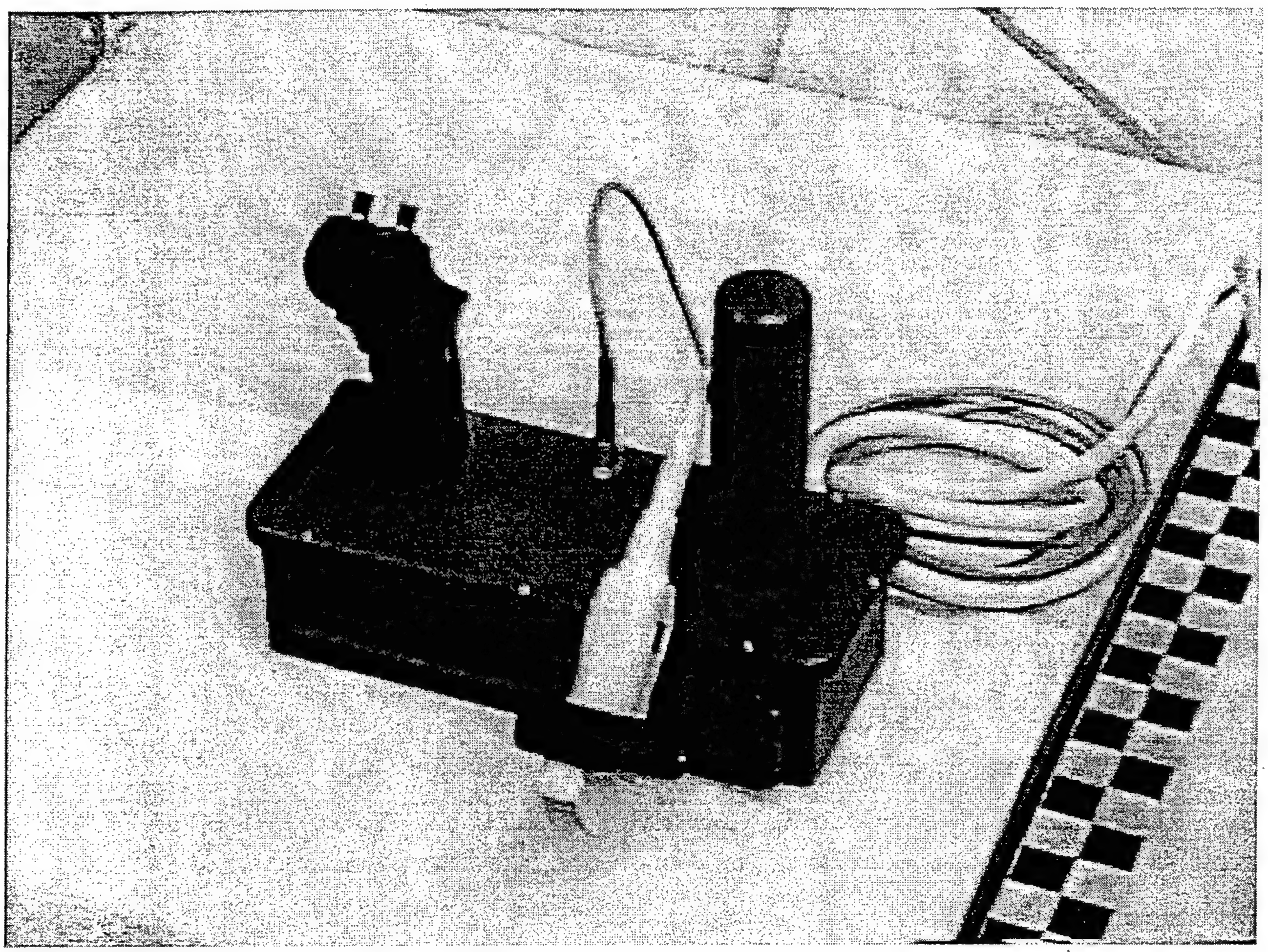
External appearance of cases (1" grid)



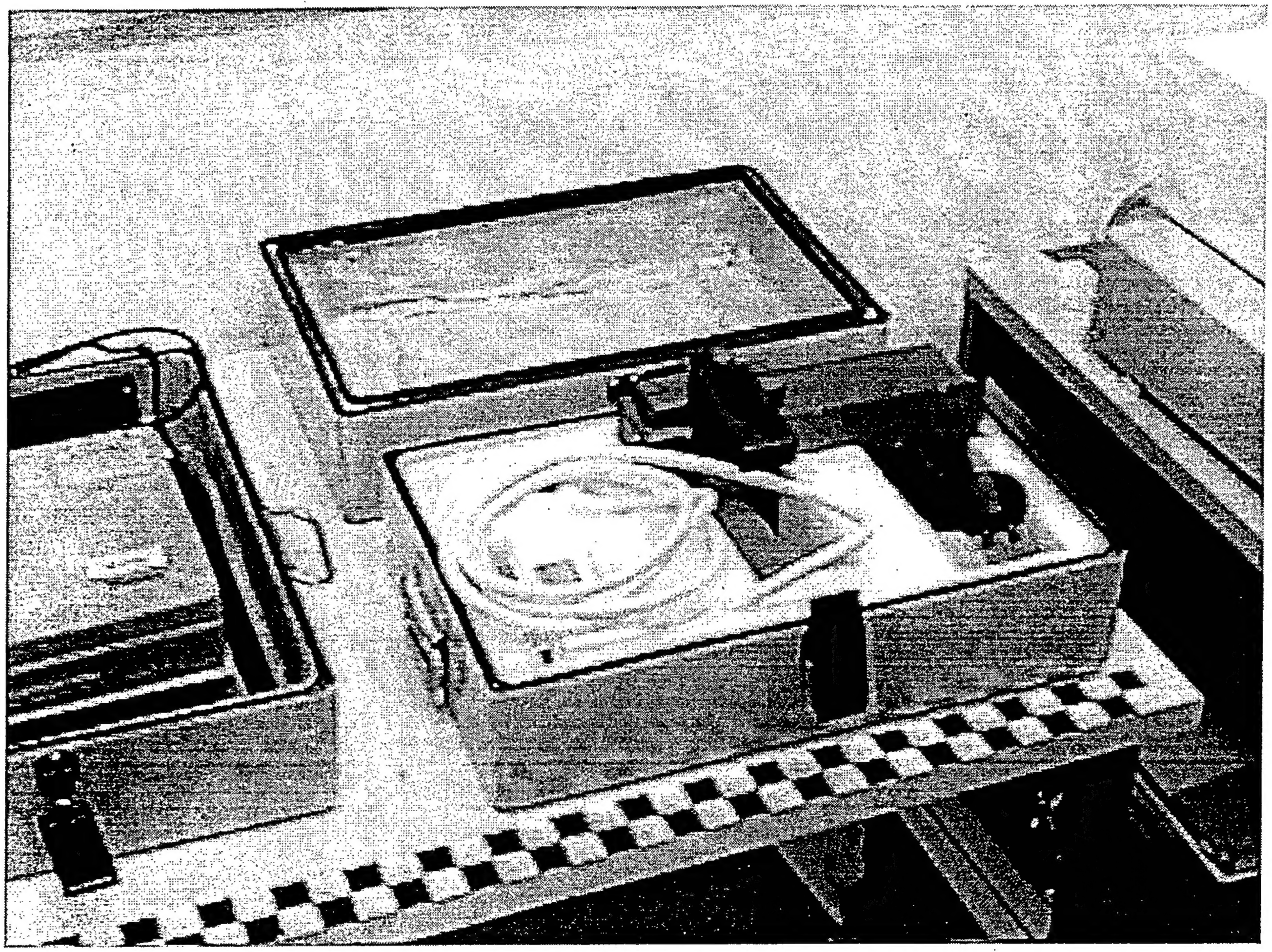
Operating configuration



Operating configuration with 3-D Paddle



Closeup of 3-D Paddle Scanner



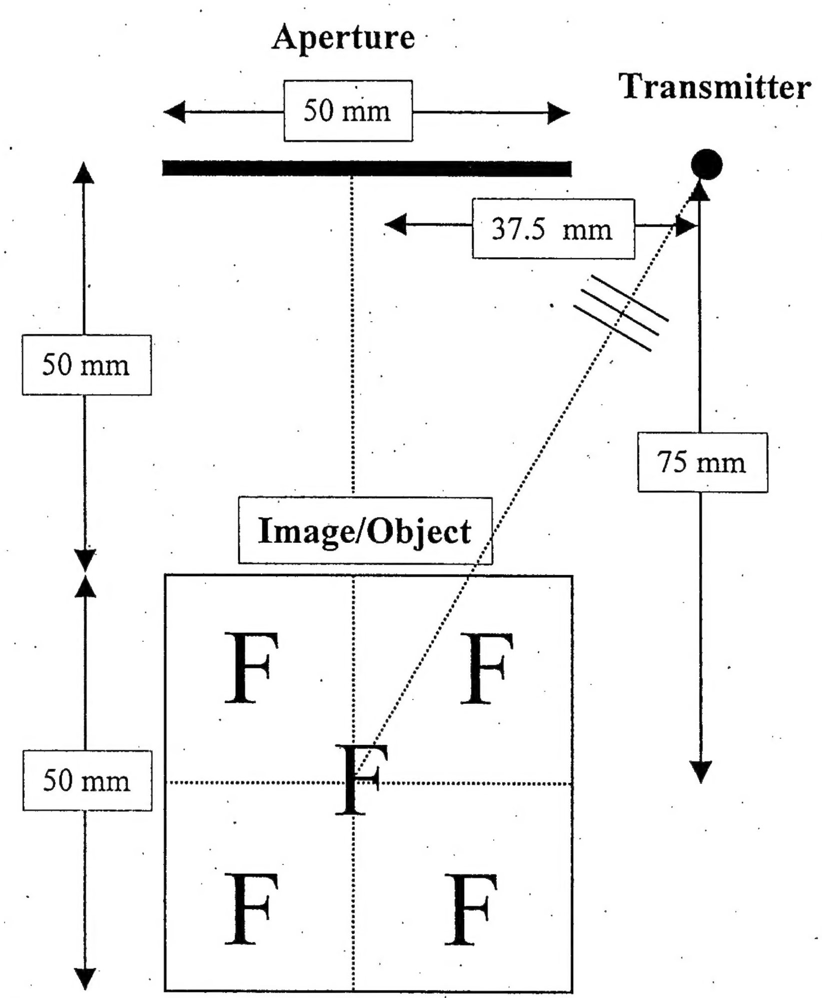
Stowed 3-D Paddle and Ultrasound Probe

Packaging team members: further construction details are available here.

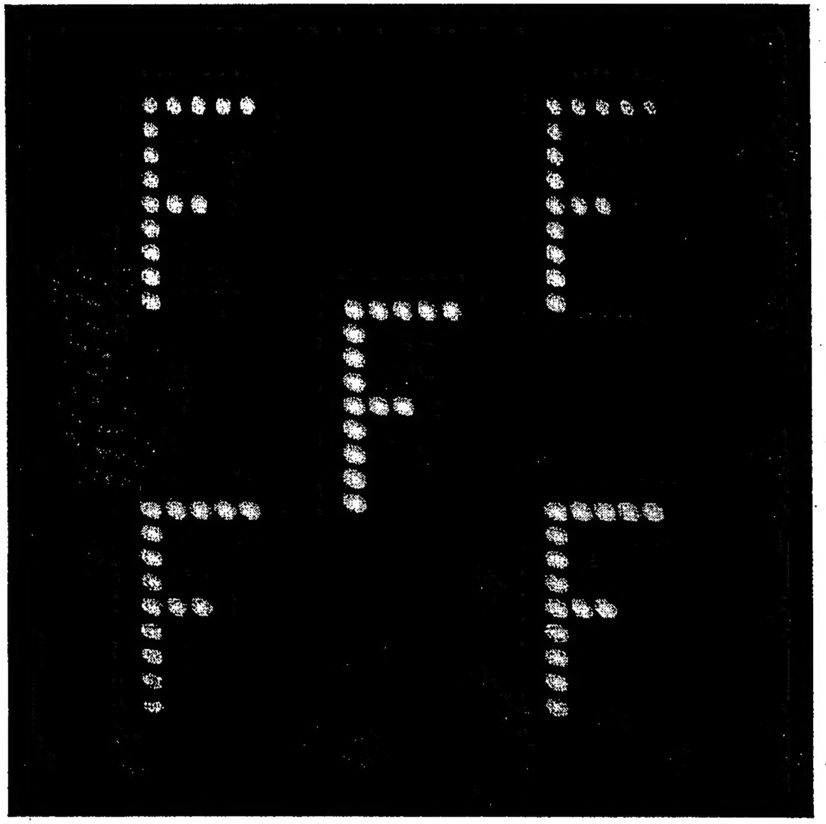
Appendix 8:

Computational Focusing – Support for Off-Axis Spherical Illumination with 2-D Array Sensors

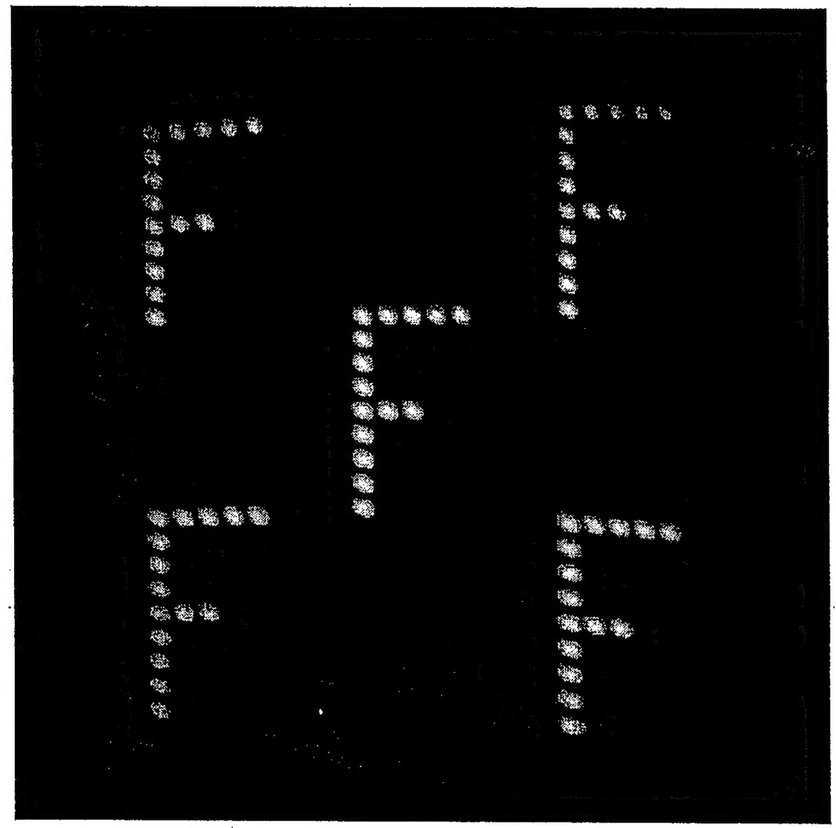
2-D Simulation/Reconstruction Configuration



Oblique Plane-wave based Reconstruction



Plane-wave Illumination



Spherical-wave Illumination

Frequency range: 4 - 6 MHz
Image size 50 mm by 50 mm
Aperture width is 50 mm

Source is at 37.5 mm, 75 mm
Range is 50 mm to 100 mm (F-1 to F-2)
Point spacing is 1.5 mm